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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code sections 2B.5A and 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay or suspension imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

Agriculture and Land Stewardship Department[21]

Replace Chapter 96

Insurance Division[191]

Replace Chapter 15

Environmental Protection Commission[567]

Replace Analysis

Replace Chapter 9

Replace Chapter 20

Replace Chapters 22 and 23

Replace Chapter 25

Replace Chapter 30

Replace Chapter 33

Replace Chapter 50

Natural Resource Commission[571]

Replace Analysis

Replace Chapter 40

Replace Chapter 44

Replace Chapter 54

Replace Chapter 81

Replace Chapter 91

Replace Chapter 113

Public Health Department[641]

Replace Analysis

Replace Chapters 37 to 41

Replace Chapter 45

Replace Chapter 55

Replace Chapter 196

Veterinary Medicine Board[811]

Replace Analysis

Replace Chapters 5 and 6

Replace Chapter 10

CHAPTER 96
HEMP

21—96.1(204) Definitions.

“Acceptable hemp THC concentration” means when an official laboratory tests a sample, the laboratory must report the delta-9 tetrahydrocannabinol (THC) content concentration on a dry weight basis and the measurement uncertainty. The acceptable hemp THC concentration is for the purpose of compliance when the application of the measurement uncertainty to the reported THC concentration on a dry weight basis produces a distribution or range that includes 0.3 percent or less. For example, if the reported THC concentration on a dry weight basis is 0.35 percent and the measurement uncertainty is +/- 0.06 percent, the measured THC concentration on a dry weight basis for this sample ranges from 0.29 percent to 0.41 percent. Because 0.3 percent is within the distribution or range, the sample is within the acceptable hemp THC concentration for the purpose of compliance. This definition of “acceptable hemp THC concentration” affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of “marihuana,” 21 U.S.C. 802(16), in the CSA.

“Applicant” means any of the following:

1. An individual with 5 percent, or more, legal or equitable interest in the hemp crop.
2. An individual applying as a member of a business entity, if that individual’s legal or equitable interest in the business entity is 5 percent or more.
3. Key participants in a corporate entity at the executive levels including chief executive officer, chief operating officer and chief financial officer.
4. If an applicant is acting on behalf of an institution governed by the state board of regents, as defined in Iowa Code section 262.7, or a community college, as defined in Iowa Code section 260C.2, “applicant” means the individual, or individuals, appointed by the president or chancellor of the institution to obtain hemp permits from the department. Other institutions of higher learning may also apply by designating an appropriate authorized representative.
5. If an applicant is acting on behalf of an association, the association shall designate an authorized representative.

“Authorized representative” means an individual designated by an applicant to act on behalf of and represent the applicant in communicating with the department for the purposes of applying for a license, submitting reports, receiving documents and information from the department, and acting as the sole primary contact pertaining to the license. An applicant may only have one authorized representative. An authorized representative shall not be a business entity.

“Business entity” means an organization created or operated by one or more individuals to carry on a trade or business.

“Cannabis” means a genus of flowering plants in the family Cannabaceae of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. Cannabis refers to any form of the plant in which the delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined.

“Certificate of analysis” means the certificate issued by the department following the official preharvest inspection, sampling and testing for total tetrahydrocannabinol (THC) concentration if the THC concentration is 0.3 percent or less by dry weight matter. The certificate of analysis shall contain the results of the department’s official laboratory test of the postdecarboxylation value concentration of the officially sampled hemp crop following the preharvest report. The certificate of analysis shall be combined with a certificate of crop inspection.

“Controlled Substances Act” or *“CSA”* means the Controlled Substances Act as codified in 21 U.S.C. 801, et seq.

“Crop site” or *“site”* means a single contiguous parcel of land suitable for the planting, growing, or harvesting of hemp, if the parcel does not exceed 40 acres. All the area within the contiguous parcel is part of the crop site. Unplanted areas, including spacing between planted rows, are part of the crop site for purposes of determining the size of a parcel. The crop site shall not be a dwelling.

“*Cultivar*” means a group of cultivated plants that are not necessarily true to type, or plants whose seed will yield the same type of plant as the original plant. A cultivar may originate as a mutation or may be a hybrid of two plants. To further develop into a variety, or propagate true-to-type clones, cultivars must be propagated vegetatively through cuttings, grafting, and even tissue culture.

“*Decarboxylated*” means the completion of the chemical reaction that converts THC-acid (THCA) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums up delta-9-THC and 87.7 percent of THCA.

“*Decarboxylation*” means the removal or elimination of a carboxyl group from a molecule or organic compound.

“*Department*” means the Iowa department of agriculture and land stewardship.

“*Destruction*” means the procedure to render unusable by burning, incorporating with other materials, or other methods approved by the department.

“*Destruction report*” means the report and notice that shall be submitted to the department on the required departmental form, no more than 48 hours after the crop has been destroyed, as ordered by the department.

“*Drug felony conviction report*” means a mandatory report submitted within 14 days of the conviction to the department on the required departmental form by any authorized representative or applicant who is convicted of a disqualifying felony offense.

“*Dry weight basis*” means the ratio of the amount of dry solid in a sample after drying to the total mass of the sample before drying, including the moisture in a sample. Dry weight basis is the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

“*Dwelling*” means a residence and all permanent or temporary structures attached to the residence.

“*Entity*” means a corporation, joint-stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization participating in the production of hemp, including but not limited to as a partner, joint venture, or other relationship.

“*Farm Service Agency*” or “*FSA*” means the Farm Service Agency of the United States Department of Agriculture.

“*Geospatial location*” means a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

“*Hemp*” means:

1. The plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis when tested using postdecarboxylation or other similarly reliable methods.

2. A plant of the genus *Cannabis* other than *Cannabis sativa* L., with a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis when tested using postdecarboxylation or other similarly reliable methods, but only to the extent allowed by the department in accordance with applicable federal law, including the federal hemp law.

“*Hemp bill of lading*” means a document of title evidencing the receipt of hemp for shipment issued by an individual engaged in the business of directly or indirectly transporting or forwarding hemp. The term does not include a warehouse receipt. The term does not include hemp transported within the state of Iowa by a person for that person’s sole use. A hemp bill of lading shall include the following:

1. The name and address of the owner of the hemp;
2. The point of origin;
3. The point of delivery, including name and address;
4. The kind and quantity of packages or, if in bulk, the total quantity of hemp in the shipment; and
5. The date of shipment.

“*High-performance liquid chromatography*” or “*HPLC*” means a type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture.

HPLC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds.

“Individual” means a single human being. An entity is not an individual.

“Indoor crop site” means:

1. A structure covered with transparent material, such as glass or polyurethane, which is specifically designed, constructed and used for the culture and propagation of hemp. Common industry terms for indoor crop sites include, but are not limited to, greenhouse, glasshouse, and hothouse; or
2. A structure, or a room within a structure, used for the culture and propagation of hemp.

“License” means a license granted by the department to grow hemp in Iowa.

“License application” means the department’s form submitted to obtain a license to grow hemp in Iowa.

“Lot” means a contiguous area in a field, greenhouse, or indoor crop site containing the same variety, cultivar, or strain of cannabis throughout. No plant within a lot shall be planted more than 14 days after the initial plant or seed was planted. In addition, “lot” is a common term in agriculture that refers to the batch or contiguous, homogeneous whole of a product being sold to a single buyer at a single time. For the purpose of this chapter, “lot” is to be defined by the producer in terms of farm location, field acreage, variety, cultivar or strain and to be reported as such to the FSA.

“Map” means a diagram depicting all borders of the crop site including the nearest roads to aid in orientation, the cardinal direction north, and the boundaries of the legally described parcel in which the crop site is located. A map designating an outdoor crop site shall clearly indicate the names, or lot numbers, of all lots and planting locations. If multiple varieties, cultivars, or strains are planted, or if the crop site shall be subdivided into separate lots for the official laboratory test, the map shall indicate the lots and sub-lots with names of the varieties, cultivars, or strains.

“Measurement uncertainty” or *“MU”* means the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could be reasonably attributed to the particular quantity subject to measurement.

“Official laboratory test” means a test of postdecarboxylation value concentration performed by the department. The laboratory quantitative determination of the THC concentration shall use postdecarboxylation and be measured using gas chromatography with flame ionization detector (GS-FID), high performance liquid chromatography (HPLC) or another acceptable method as determined by the department.

“Official sample” means the preharvest hemp sample collected by the department, in accordance with department policy, which is used to assess the THC concentration of a single lot of hemp.

“Order of destruction” means the order furnished to the licensee by the department, in consultation with the department of public safety, ordering the destruction of cannabis that exceeds the acceptable hemp THC concentration.

“Outdoor crop site” means any crop site that is not an indoor crop site.

“Planting report” means the report and notice submitted to the department on the required departmental planting report form. Planting reports are required for both indoor and outdoor hemp crops.

“Postdecarboxylation value,” in the context of testing methodologies for THC concentration in hemp, means a value determined after the process of decarboxylation that determines the total potential delta-9 tetrahydrocannabinol (THC) content derived from the sum of the THC and delta-9-tetrahydrocannabinolic acid (THCA) content and reported on a dry weight basis. The postdecarboxylation value of THC can be calculated by using a chromatographic technique using heat, gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The postdecarboxylation value of THC can also be calculated by using a high-performance liquid chromatograph technique, which keeps the THCA intact and requires a conversion calculation of that THCA to calculate total potential THC in a given sample.

“*Postharvest report*” means the report and notice that the licensee shall deliver to the department on the required departmental postharvest report form, no more than 30 days after the harvest of a lot is complete.

“*Preharvest inspection*” means the inspection to collect one or more official samples for official laboratory testing.

“*Preharvest report*” means the report and notice that the licensee shall deliver to the department on the required departmental preharvest form in order to request a preharvest inspection. The licensee shall submit the preharvest report no less than 30 days prior to the expected harvest date of any hemp crop.

“*Reverse distributor*” means a person who is registered with Drug Enforcement Administration (DEA) in accordance with 21 CFR 1317.15 to dispose of marijuana under the Controlled Substances Act.

“*Strain*” means variations of a cultivar, generally from breeding techniques or genetic mutations.

“*Sub-lot*” means an area divided from a larger lot. A lot may be divided into multiple sub-lots.

“*Temporary harvest and transportation permit*” means a temporary and limited permit issued by the department when the official sample is taken, allowing the harvest and transportation of the officially tested crop prior to the completion of official laboratory sampling.

“*THC*” means total tetrahydrocannabinol as determined by an official laboratory test postdecarboxylation.

“*Variety*” means a plant grouping within a single botanical taxon of the lowest known rank that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.2(204) Licensing. A license to grow hemp shall be obtained from the department. In order to obtain and maintain a license, an applicant shall submit a license application, receive approval from the department, and comply with the standards contained in Iowa Code chapter 204 and these rules.

96.2(1) A license is nontransferable unless approved by the department.

96.2(2) In 2020, the license application for an outdoor crop site shall be submitted to the department on or before May 15. Indoor crop site applications may be submitted at any time.

96.2(3) In 2021 and thereafter, the license application for an outdoor crop site shall be submitted to the department on or before April 15. Indoor crop site license applications may be submitted at any time.

96.2(4) Failure to include all applicants shall preclude the license application from consideration.

96.2(5) Applicants shall submit an application form. A complete application form shall include, at a minimum, the following:

- a. The authorized representative’s full name and mailing address.
- b. A legal description and map of each crop site where the applicant proposes to produce hemp.
- c. The geospatial location of the center of the crop site.
- d. The number of crop acres intended for hemp production. For fractions of acres, round to the next whole number.
- e. The name of the hemp varieties, cultivars or strains proposed to be grown by the applicant.
- f. The intended hemp crop to be grown by the applicant; this includes grain, seed, fiber, cannabidiol (CBD), clones, cuttings, plantlets, or other identifying information.
- g. The type of crop site (indoor or outdoor).
- h. All parties with an ownership interest in the crop site or hemp crop. If the crop site is leased, the name and contact information of all lessors and lessees with any interest in the crop site or hemp crop shall be provided.

i. The destruction method the applicant intends to use to destroy the cannabis if the crop fails to meet the acceptable hemp THC concentration. The destruction method must be approved by the department prior to actual destruction.

96.2(6) The authorized representative and all applicants shall submit official fingerprints to the department as a part of the application process. All national criminal history record check fees shall be paid to the department.

96.2(7) All license applications shall be submitted to the department electronically via the online license application portal. An authorized representative may request a waiver from the department to submit an application through an alternative format.

96.2(8) Real-time information, including but not limited to the status and number of the producer's license, shall be accessible via the department's online license application portal. Information submitted to the department via the online license application portal shall be collected, maintained, and reported to the USDA as required by the USDA in 7 CFR Part 990, Subpart C.

96.2(9) A license expires on December 31 of the year the license is issued.

96.2(10) An applicant with a state or federal felony conviction relating to a controlled substance is subject to a ten-year ineligibility from the date of the conviction.

96.2(11) Any applicant who materially falsifies any information contained in an application shall be ineligible for a license.

96.2(12) The department may implement additional reasonable licensing requirements at its discretion.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.3(204) National criminal history record check.

96.3(1) Disqualifying offenses.

a. An applicant shall not be convicted of, or plead guilty to, a disqualifying felony offense. All applicants shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

b. The department or the department of public safety may request additional information to complete a background investigation and national criminal history background check. An applicant or authorized representative shall respond within 30 days to any request for additional information. Failure to timely respond shall result in a denial of the license application.

c. The department may deny any application for good cause.

96.3(2) An applicant and authorized representative shall provide fingerprints to the department. The department shall provide the fingerprints to the department of public safety for submission through the state criminal history repository to the federal bureau of investigation.

96.3(3) The applicant shall pay the actual cost of conducting any national criminal history record check to the department.

96.3(4) The results of a national criminal history check may be valid for three consecutive license years unless a drug-related felony conviction occurs after the issuance of the national criminal history record check results.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.4(204) Licensee reports.

96.4(1) *Planting report.*

a. Outdoor planting report. Within 14 days after planting an outdoor hemp crop, the authorized representative shall submit a planting report to the department. The planting report does not constitute the required preharvest report. The planting report shall be on a form prepared and distributed by the department that shall include, but is not limited to:

- (1) The authorized representative's full name and contact information.
- (2) The license number.
- (3) The anticipated harvest date.
- (4) An updated detailed map depicting any changes.

b. Indoor planting report. On the first day of the month following any planting activity in the immediately preceding month, the authorized representative shall submit a planting report. The planting report does not constitute the required preharvest report. The planting report shall be on a departmental form prepared and distributed by the department. The planting report form shall include, at a minimum, the following:

- (1) The authorized representative's full name and contact information.
- (2) The license number.
- (3) The anticipated harvest date.

96.4(2) Preharvest report. The authorized representative shall submit a preharvest report to the department no less than 30 days prior to the expected harvest date of the hemp crop produced at the licensee's crop site. The licensee shall be entirely responsible for determining the expected harvest date for the hemp crop. The preharvest report shall be on a departmental form prepared and distributed by the department. The preharvest report form shall include, at a minimum, the following:

- a.* The authorized representative's full name and contact information.
- b.* The license number.
- c.* The anticipated date range for initiating and completing harvest, recorded by lot.
- d.* A map of the outdoor crop site. If more than one harvest date is being reported for the lots within the crop site, the map shall designate the locations of the lots, and the intended harvest dates, which are to be harvested under the preharvest report.

96.4(3) Postharvest report. The licensee shall deliver the postharvest report to the department no less than 14 days after the harvest of a lot is complete. If any lots within a crop site are harvested at different times, each harvest date shall be independently recorded by lot. The postharvest report shall be on a departmental form prepared and distributed by the department. The postharvest report form shall include, at a minimum, the following:

- a.* The authorized representative's full name and contact information.
- b.* The license number.
- c.* The harvest date(s).
- d.* The independent harvest date of each lot.

96.4(4) Destruction report. The licensee shall deliver a destruction report no more than 48 hours after crop destruction, or as ordered by the department. The destruction report shall be on a form prepared and distributed by the department. The destruction report shall include, but is not limited to:

- a.* The authorized representative's full name and contact information.
- b.* The license number.
- c.* The destruction date(s).
- d.* The method of destruction.
- e.* The independent destruction date of each lot.

96.4(5) Drug felony conviction report. Any authorized representative or applicant who is convicted of, or pleads guilty to, a disqualifying felony offense must report the disqualifying offense to the department and any co-licensees within 14 days of the conviction. The offender shall immediately forfeit the license. In the case of multiple licensees holding a single license, the offender's interest in the license shall be immediately terminated. Failure to report the disqualifying offense may result in an order of destruction. The drug felony conviction report shall be on a form prepared and distributed by the department that shall include, but is not limited to:

- a.* The license number(s).
- b.* The name and contact information for the individual reporting the individual's conviction.
- c.* The date of conviction.
- d.* An acknowledgment that all co-licensees have been informed of the disqualifying offense, if applicable, and the co-licensees have assumed full responsibility for the hemp crop.

96.4(6) Hemp acreage report to the FSA. Within 30 days after the completion of planting of an outdoor crop site, or within 30 days after the first planting of hemp in the calendar year in an indoor crop site, the authorized representative shall report the hemp acreage to the FSA. At a minimum, the following information shall be reported:

- a. Street address and geospatial location for each crop site.
- b. Acreage for each crop site.
- c. The license number.

96.4(7) Voluntary destruction report. If a licensee chooses to destroy a lot prior to harvest, the authorized representative shall notify the department of the licensee’s intent to destroy the crop within seven days prior to the destruction. The hemp crop shall not be destroyed unless the department or local law enforcement either is present during the destruction or has authorized destruction to occur unwitnessed. The voluntary destruction report shall be on a form prepared and distributed by the department that shall include, but is not limited to:

- a. The authorized representative’s full name and contact information.
- b. The license number.
- c. The date(s) and method of destruction for each lot.
- d. The identification number or name of the lot(s).
- e. The reason for destruction.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.5(204) Fees. The department shall impose, assess, and collect fees, which shall be paid by a licensee. All fees shall be collected by the department before the department takes any action for which the fee is applicable. All fees are nonrefundable.

96.5(1) The license fee shall be paid prior to acceptance of a license application. License fees shall be based on the number of acres in a crop site, as follows:

TABLE 1
LICENSE FEES PER CROP SITE

Acres	Fee	
0 - 5	\$500 + \$5 per acre	Paid at application
5.1 - 10	\$750 + \$5 per acre	
10.1 - 40	\$1,000 + \$5 per acre	

96.5(2) A primary base fee shall be paid prior to acceptance of a license application. Payment of a primary base fee shall secure the preharvest inspection. The preharvest inspection shall include the collection of an official sample and an official test of that sample. Prior to, or during, the preharvest inspection, a licensee may request official sampling of additional lots and sub-lots. A primary supplemental fee shall be charged for each additional official sample and official test. All primary supplemental fees shall be paid prior to performance of any official test, as follows:

TABLE 2
PRIMARY FEES

Primary Base Fee	Primary Supplemental Fee
\$1,000 per sample	\$500 per sample
Paid at application	Paid prior to official sampling

96.5(3) A licensee may request one or more secondary preharvest inspections. Payment of a secondary base fee shall secure a secondary preharvest inspection. The secondary preharvest inspection shall include the collection of an official sample and an official test of that sample. Prior to, or during, any sampling, a licensee may request official sampling of additional lots and sub-lots. A secondary supplemental fee shall be charged for each additional official sample and official test. All secondary supplemental fees shall be paid prior to performance of any official test, as follows:

TABLE 3
SECONDARY FEES

Secondary Base Fee	Secondary Supplemental Fee
\$1,000 per sample	\$500 per sample
Paid prior to official sampling	Paid prior to official sampling

96.5(4) A licensee may request a single retest of a sample collected for a lot or sub-lot if the licensee believes the original official laboratory test result was in error. The licensee may not request the collection of a new sample. The licensee requesting the retest of the sample shall pay the retest fee prior to performance of official retest. The retest fee shall be \$500.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.6(204) Annual review of licensees to ensure licensure compliance.

96.6(1) The authorized representative shall certify the licensee has operated and will continue to operate in accordance with Iowa Code chapter 204 by executing a certification of compliance as part of the harvest report, by answering the following questions:

- a. Have you operated in accordance with all license requirements?
- b. Has any of the following information changed?

(1) The authorized representative and all individual applicants' full names, titles, residential addresses, phone numbers, or email addresses.

- (2) Key participant title in the business entity.
- (3) The structure of or ownership interests in the business entity.

c. Were the hemp acres at the crop site reported to the FSA?

d. Have any hemp plants been harvested or removed from the crop site prior to official sampling and official testing?

96.6(2) Crop sites that do not harvest hemp and solely propagate cuttings and clones shall be inspected at least annually.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.7(204) Sampling procedures for official testing of hemp for THC content.

96.7(1) The licensee shall submit a preharvest report to the department at least 30 days prior to the anticipated harvest date.

96.7(2) Official samples for official testing shall be collected by the department or a third-party sampler designated by the department.

96.7(3) The authorized representative, or licensee, shall be present at any preharvest inspection and official sampling of the crop site.

96.7(4) The department inspector will verify the geospatial location coordinates submitted to the department.

96.7(5) The licensee must allow complete and unrestricted access to the crop site. If the licensee fails to provide unrestricted access, an official sample will not be collected.

a. If cannabis plants are observed outside of the crop site boundaries, the department shall notify law enforcement.

b. If the department inspector suspects that the licensee harvested hemp plants prior to official sampling, the department inspector will immediately cease official sampling and notify the Iowa hemp program administrator. The Iowa hemp program administrator shall determine how to proceed with an investigation, seeking law enforcement assistance as necessary.

96.7(6) A separate official sample shall be taken for each lot and sub-lot. In accordance with the fee schedule established by the department, a supplemental fee shall be charged for every sample after one sample.

96.7(7) If the licensee chooses to have official samples taken from sub-lots within a lot, the boundary between sub-lots shall be discernable. In an outdoor crop site, the minimum row space between lots and sub-lots shall be twice the normal row spacing, but no less than 36 inches.

96.7(8) The department inspector shall take a representative official sample of each lot and sub-lot, walking at right angles to the rows if possible. The department inspector may take more cuttings than the minimum listed in Table 4 if necessary to obtain an adequate official sample.

96.7(9) The official sample collected by the department shall consist of approximately 2-inch cuttings of flowering material, meaning inflorescences (the flower or bud of plant), from the top one-third of the plant, based on the following table:

TABLE 4
NUMBER OF PLANTS SAMPLED, BASED ON LOT AND SUB-LOT ACREAGE SIZE

Number of acres	Number of plants sampled	Number of acres	Number of plants sampled	Number of acres	Number of plants sampled	Number of acres	Number of plants sampled
1	10	11	11	21	20	31	29
2	10	12	12	22	21	32	29
3	10	13	13	23	22	33	30
4	10	14	14	24	23	34	31
5	10	15	15	25	24	35	32
6	10	16	16	26	24	36	33
7	10	17	17	27	25	37	34
8	10	18	18	28	26	38	34
9	10	19	18	29	27	39	35
10	10	20	19	30	28	40	36

96.7(10) The plants and plant material selected for official sampling shall be determined solely by the department.

96.7(11) All samples shall become the property of the department and are nonreturnable.

96.7(12) The department inspector will place the official composite representative sample in a properly labeled paper bag. The labeled bag will be sealed with security tape, and the following information shall be placed on the paper bag:

- a. License number;
- b. Name and contact information of the sampling agent;
- c. Name and contact information of the licensee;
- d. Date sample was taken;
- e. Sample identification number for the lot or sub-lot;
- f. Parcel identification number from the FSA; and
- g. Any other information that may be required by the department.

96.7(13) The official sample and sampling report shall be hand-delivered or placed in a box, sealed with security tape, and overnight shipped to the department laboratory.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.8(204) Approved testing methods of hemp for THC content.

96.8(1) The department laboratory shall be the only official laboratory for analyzing official samples from licensed crop sites in Iowa.

96.8(2) An appropriate chain of custody will be maintained at all times, and the information from the sampling form will be input into the department laboratory information management system.

96.8(3) The official samples will be dried, the stem and seed will be separated from floral material and discarded, and the floral material will be ground.

96.8(4) The ground floral material will be tested for THC content.

- a. Any remaining floral material will be retained by the department for three months.
- b. If a licensee requests a single retest of a lot or sub-lot, the department shall retest any remaining floral material.

96.8(5) The THC concentration will be determined by gas-liquid chromatography (GC) or other acceptable method as determined by the department.

96.8(6) The department will utilize MU in determining acceptable hemp THC concentration.

96.8(7) If the official laboratory test results in the acceptable hemp THC concentration, the department shall issue a certificate of analysis, as provided in Iowa Code section 204.8, and immediately send the certificate of analysis to the authorized representative.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.9(204) Harvesting timing.

96.9(1) A licensee shall not harvest any portion of a hemp crop unless the department has officially sampled the lot to be harvested.

96.9(2) The licensee may begin harvesting the corresponding lots and sub-lots upon receiving a temporary harvest and transportation permit. The temporary harvest and transportation permit will expire once a certificate of analysis, or destruction order, is issued.

a. Prior to receiving the temporary harvest and transportation permit, the licensee shall designate a storage site for the hemp crop. The licensee shall ensure that the department has unrestricted access to the crop at all times, including, if necessary, to fulfill an order of destruction. The harvested crop shall remain at the designated storage site until a certificate of analysis, or order of destruction, is issued.

b. The designated storage site must be within the state of Iowa.

c. All harvested lots and sub-lots shall be stored in a manner that preserves identity, regardless of the form, condition, or location of the crop. There shall be no commingling of separate harvested hemp lots.

96.9(3) Until the certificate of analysis is received, ownership of the hemp crop shall not change.

a. The licensee shall harvest an officially sampled hemp lot no later than 15 days after the lot was officially sampled. If the licensee has not completed harvest within 15 days and still desires to harvest any remaining crop, the licensee shall contact the department and request supplemental official sampling and official laboratory tests.

b. The day the crop site is officially sampled shall be considered day 0. The next day is considered day 1 after sampling, and so on, until day 15.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.10(204) Order of destruction.

96.10(1) If the official laboratory test does not result in an acceptable hemp THC concentration, the department shall order the destruction of the hemp crop to occur as ordered by the department.

96.10(2) If any official test exceeds acceptable hemp THC concentration, the department shall notify the department of public safety, local law enforcement, and the United States Department of Agriculture (USDA) hemp administrator.

96.10(3) If any official test exceeds 0.5 percent THC on a dry weight basis, the department shall notify the department of public safety, local law enforcement, the USDA hemp administrator, and the United States attorney general.

96.10(4) If any official test result exceeds 2.0 percent THC on a dry weight basis, the department shall notify the department of public safety, local law enforcement, the USDA hemp administrator, the United States attorney general, the county attorney, and the Iowa attorney general.

96.10(5) Failure to harvest any portion of a hemp lot 15 or more days after the lot was officially sampled may result in the issuance of an order of destruction.

96.10(6) The department may require the licensee to utilize a reverse distributor for destruction.

96.10(7) The department shall notify the USDA hemp administrator when the destruction is complete.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.11(204) Negligent violations.

96.11(1) Negligent violations shall include but are not limited to:

a. The production of hemp that exceeds the acceptable hemp THC concentration but is less than 0.5 percent THC on a dry weight basis.

b. Failure to submit required reports within mandated submission deadlines.

c. Failure to provide a legal description of the land on which the licensee produces hemp.

The department may determine additional negligent violations as needed.

96.11(2) All licensees associated with the license shall receive the negligent violation.

96.11(3) The failure to obtain a license is not a negligent violation.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.12(204) Negligent violation program.

96.12(1) The department shall require the completion of a corrective action plan for negligent violations. A licensee shall submit a corrective action plan to the department for consideration and approval. A corrective action plan shall consist of the following:

a. A reasonable time period, approved by the department, for correcting a negligent violation. Failure to correct a negligent violation within the reasonable time period shall be considered an additional negligent violation.

b. A proposed schedule for the licensee to submit periodic compliance reports to the department, when applicable. The duration for the ongoing compliance reports shall not be less than two calendar years following the violation.

c. Any other requirement established by the department.

96.12(2) The department may conduct any inspection, review, or other action to determine if the corrective action plan has been implemented as approved by the department.

96.12(3) The department shall issue a certificate of completion to the licensee upon the successful completion of the corrective action plan.

96.12(4) A licensee who is participating in, or who successfully completes, the corrective action plan shall not be subject to any criminal enforcement action pertaining to the negligent violations by the federal, state, tribal, or local government.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

21—96.13(204) State plan. The department has adopted a state plan, as prescribed by the United States Department of Agriculture, in order to assume primary regulatory authority over the production of hemp in Iowa.

[ARC 5050C, IAB 6/17/20, effective 7/22/20]

These rules are intended to implement Iowa Code section 204.3.

[Filed Emergency ARC 4842C, IAB 1/1/20, effective 12/11/19]

[Filed Emergency ARC 4989C, IAB 3/11/20, effective 2/24/20]

[Filed ARC 5050C (Notice ARC 4988C, IAB 3/11/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 15
UNFAIR TRADE PRACTICES
[Prior to 10/22/86, Insurance Department[510]]

DIVISION I
SALES PRACTICES

191—15.1(507B) Purpose. This chapter is intended to establish certain minimum standards and guidelines of conduct by identifying unfair methods of competition and unfair or deceptive acts or practices in the business of insurance, as prohibited by Iowa Code chapter 507B.

191—15.2(507B) Definitions.

“Advertisement” for the purpose of these rules shall be material designed to create public interest in insurance or an insurer, or to induce the public to purchase, increase, modify, reinstate or retain a policy including:

1. Printed and published material, audio and visual material, and descriptive literature of an insurer or producer used in direct mail, newspapers, magazines, radio scripts, TV scripts, billboards, computer on-line networks and similar displays; descriptive literature and sales aids of all kinds issued by an insurer or producer for presentation to members of the public, including but not limited to circulars, leaflets, booklets, depictions, illustrations, and form letters; and sales talks, presentations, and material for use by producers.

2. However, for the purpose of these rules “advertisement” shall not include: communications or materials used within an insurer’s own organization and not intended for dissemination to the public; communications with policyholders other than material urging policyholders to purchase, increase, modify, reinstate, or retain a policy; and a general announcement from a group or blanket policyholder to eligible individuals on an employment or membership list that a policy or program has been written or arranged, provided the announcement clearly indicates that it is preliminary to the issuance of a booklet explaining the proposed coverage.

“Aftermarket crash parts” means replacement parts as defined in Iowa Code section 537B.4.

“Certificate” means a statement of the coverage and provisions of a policy of group accident and sickness insurance which has been delivered or issued for delivery in this state and includes riders, endorsements and enrollment forms, if attached.

“Duplicate Medicare supplement insurance” shall mean the sale or the attempt to knowingly sell to an individual a policy of insurance designed to supplement Medicare benefits as provided in The Health Insurance for the Aged Act, Title XVII of the Social Security Amendments of 1965 as then constituted or later amended when the individual is already insured under such a policy.

“Duplication” means policies of the same coverage type according to minimum standards classifications outlined in 191 IAC 36.6(514D) which overlap to the extent that a reasonable individual would not consider the ownership of the policies to be beneficial.

“Exception” for the purpose of these rules shall mean any provision in a policy whereby coverage for a specified hazard is entirely eliminated; it is a statement of a risk not assumed under the policy.

“Illustrated scale” shall mean a scale of nonguaranteed elements currently being illustrated that is not more favorable to the policyholder than the lesser of the disciplined current scale or the currently payable scale as defined in 191 IAC 14.4(507B).

“Institutional advertisement” means an advertisement having as its sole purpose the promotion of the reader’s, viewer’s or listener’s interest in the concept of accident and sickness insurance, or the promotion of the insurer as a seller of accident and sickness insurance.

“Insurer” shall mean any corporation, association, partnership, reciprocal exchange, interinsurer, Lloyd’s, fraternal benefit society, and any other legal entity engaged in the business of insurance.

“Invitation to contract” means an advertisement for accident and sickness insurance that is neither an invitation to inquire nor an institutional advertisement.

“Invitation to inquire” means an advertisement having as its objective the creation of a desire to inquire further about accident and sickness insurance and that is limited to a brief description of the loss

for which benefits are payable. An invitation to inquire may not refer to cost but may contain the dollar amount of benefits payable and the period of time during which benefits are payable.

“*Limitation*” for the purpose of these rules shall mean any provision which restricts coverage under the policy other than an exception or a reduction.

“*Limited benefit health coverage*” shall have the same meaning as defined in 191—subrule 36.6(10).

“*Person*” shall mean any individual, corporation, association, partnership, reciprocal exchange, interinsurer, fraternal benefit society, and any other legal entity engaged in the business of insurance, including insurance producers and adjusters. “*Person*” shall also mean any corporation operating under the provisions of Iowa Code chapter 514 and any benevolent association as defined and operated under Iowa Code chapter 512A. For purposes of this chapter, corporations operating under the provisions of Iowa Code chapter 514 and Iowa Code chapter 512A shall be deemed to be engaged in the business of insurance.

“*Policy*” shall include any policy, plan, certificate, contract, agreement, statement of coverage, rider, or endorsement which provides for insurance benefits.

“*Preneed funeral contract or prearrangement*” shall mean an agreement by or for an individual before the individual’s death relating to the purchase or provision of specific funeral or cemetery merchandise or services.

“*Producer*” shall mean a person who solicits, negotiates, effects, procures, delivers, renews, continues or binds policies of insurance for risks residing, located or to be performed in this state.

“*Prominently*” or “*conspicuously*” means that the information to be disclosed will be presented in a manner that is noticeably set apart from other information or images in the advertisement.

“*Reduction*” for the purpose of these rules shall mean any provision which reduces the amount of the benefit; a risk of loss is assumed but payment upon the occurrence of such loss is limited to some amount or period less than would be otherwise payable had such reduction not been used.

“*Twisting*” shall mean any action by a producer or insurer to induce or attempt to induce any individual to lapse, forfeit, surrender, terminate, retain, assign, borrow, or convert a policy or an annuity in order that such individual procure another policy or annuity, when such action would operate to the overall detriment of the interests of the individual.

191—15.3(507B) Advertising.

15.3(1) *Form and content of advertisements.* The format and content of an advertisement shall be truthful and sufficiently complete and clear to avoid deception or the capacity or tendency to misrepresent or deceive. Whether an advertisement has a capacity or tendency to misrepresent or deceive shall be determined by the overall impression that the advertisement may be reasonably expected to create upon an individual in the segment of the public to which it is primarily directed and who has average education, intelligence and familiarity with insurance terminology for products in that market.

Information regarding exceptions, limitations, reductions and other restrictions required to be disclosed by this rule shall not be minimized, rendered obscure or presented in an ambiguous fashion or intermingled with the context of the advertisements so as to be confusing or misleading.

15.3(2) *Prohibited terms and disclosure requirements for health insurance.*

a. No advertisement shall contain or use words or phrases such as “all”; “full”; “complete”; “comprehensive”; “unlimited”; “up to”; “as high as”; “this policy will help fill some of the gaps that Medicare and your present insurance leave out”; “this policy will help to replace your income” (when used to express loss of time benefits); or similar words and phrases, in a manner which exaggerates any benefits beyond the terms of the policy.

b. No advertisement shall contain descriptions of a policy limitation, exception, or reduction, worded in a positive manner to imply that it is a benefit, such as describing a waiting period as a “benefit builder” or stating “even preexisting conditions are covered after two years.” Words and phrases used in an advertisement to describe such policy limitations, exceptions and reductions shall fairly and accurately describe the negative features of such limitations, exceptions and reductions of the policy offered.

c. No advertisement of a benefit for which payment is conditional upon confinement in a hospital or similar facility shall use words or phrases such as “tax free,” “extra cash” and substantially similar

phrases which have the capacity, tendency or effect of misleading the public into believing that the policy advertised will, in some way, enable an individual to make a profit from being hospitalized.

d. No advertisement shall use the words “only”; “just”; “merely”; “minimum” or similar words or phrases to describe the applicability of any exceptions and reductions, such as: “This policy is subject to the following minimum exceptions and reductions.”

e. An advertisement which refers to either a dollar amount, or a period of time for which any benefit is payable, or the cost of the policy, or specific policy benefit, or the loss for which such benefit is payable, shall also disclose those exceptions, reductions, and limitations affecting the basic provisions of the policy without which the advertisement would have the capacity or tendency to mislead or deceive.

f. An advertisement may contain a brief description of coverage in an invitation to inquire so long as it is limited to a brief description of the loss for which benefits are payable. The brief description may also contain the dollar amount of benefits payable or the period of time during which benefits are payable, or both, but may not refer to the cost of the policy.

g. An advertisement for a policy which contains a waiting, elimination, probationary, or similar time period between the effective date of the policy and the effective date of coverage under the policy or a time period between the date a loss occurs and the date benefits begin to accrue for such loss shall prominently disclose the existence of such periods.

h. An invitation to inquire shall contain a provision in the following or substantially similar form: “This policy has [exclusions] [limitations] [reduction of benefits] [terms under which the policy may be continued in force or discontinued]. For costs and complete details of the coverage, call [or write] your insurance agent or the company [whichever is applicable].”

15.3(3) *Prohibited terms in life insurance and annuity policies.* No advertisement for a life insurance or annuity policy shall use the terms “investment,” “investment plan,” “founder’s plan,” “charter plan,” “expansion plan,” “profit,” “profits,” “profit sharing,” “interest plan,” “savings,” “savings plan,” “retirement plan,” or other similar term which has the capacity or tendency to mislead an insured or prospective insured to believe that the insurer is offering something other than an insurance policy or some benefit not available to other individuals of the same class and equal expectation of life. An advertisement shall not state that there are “no more premiums” or that premiums will “vanish” or “disappear” or use similar terms when such statement is not based on the guaranteed rates.

15.3(4) *Exclusions, limitations, exceptions and reductions.* Words and phrases used in an advertisement to describe policy exclusions, limitations, exceptions and reductions shall clearly, prominently and accurately indicate the negative or limited nature of the exclusions, limitations, exceptions and reductions.

An advertisement for a policy providing benefits for specified illnesses only, such as cancer, or other policies providing benefits that are limited in nature shall clearly and conspicuously in prominent type state the limited nature of the policy. The statement shall be worded in language identical to or substantially similar to the following: “THIS IS A LIMITED POLICY,” “THIS POLICY PROVIDES LIMITED BENEFITS,” or “THIS IS A CANCER-ONLY POLICY.”

15.3(5) *Use of statistics.* An advertisement shall not contain statistical information relating to any insurer or policy unless it accurately reflects recent and relevant facts. The source of any such statistics used in an advertisement shall be identified therein.

15.3(6) *Introductory, initial or special offers.*

a. An advertisement shall not directly or by implication represent that a policy is an introductory, initial or special offer, or that a person will receive advantages not available at a later date, or that the offer is available only to a specified group of persons, unless such is the fact.

b. An advertisement shall not offer a policy which utilizes a reduced initial premium rate in a manner which overemphasizes the availability and the amount of the initial reduced premium. When an insurer charges an initial premium that differs in amount from the amount of the renewal premium payable on the same mode, the advertisement shall not display the amount of the reduced initial premium either more frequently or more prominently than the renewal premium, and both the initial reduced

premium and the renewal premium must be stated in each portion of the advertisement where the initial reduced premium appears. This paragraph shall not apply to annual renewable term policies.

15.3(7) Testimonials or endorsements by third parties.

a. Testimonials used in advertisements must be genuine, represent the current opinion of the author, be applicable to the policy advertised and be accurately reproduced. The insurer, in using a testimonial, makes as its own all of the statements contained therein, and the advertisement, including such statement, is subject to all the provisions of these rules.

b. If the person making a testimonial or an endorsement has a financial interest in the insurer or a related entity as a stockholder, director, officer, employee, or otherwise, such fact shall be disclosed in the advertisement. If a person is compensated for making a testimonial or endorsement, such fact shall be disclosed in the advertisement by language substantially as follows: "Paid Endorsement." This rule does not require disclosure of union "scale" wages required by union rules if the payment is actually for such "scale" for TV or radio performances. The payment of substantial amounts, directly or indirectly, for "travel and entertainment" for filming or recording of TV or radio advertisements constitutes compensation and requires disclosure. This rule does not apply to an institutional advertisement which has as its sole purpose the promotion of the insurer.

c. An advertisement which states or implies that an insurer or an insurance product has been approved or endorsed by any person or other organizations must also disclose any proprietary or other relationship between the parties.

15.3(8) Disparaging and incomplete comparisons and statements. An advertisement shall not directly or indirectly make unfair or incomplete comparisons of policies or benefits or comparisons of noncomparable policies of other insurers, and shall not disparage other insurers, their policies, services or business methods, and shall not disparage or unfairly minimize competing methods of marketing insurance. An advertisement shall not contain statements which are untrue in fact, or by implication misleading, with respect to the assets, corporate structure, financial standing, age or relative position of an insurer in the insurance business.

15.3(9) Identity of insurer.

a. The name of the actual insurer shall be clearly identified in all advertisements for a particular policy. An advertisement shall not use a trade name, insurance group designation, name of a parent company, name of a particular company division, service mark, slogan, symbol or other device which would have the capacity and tendency to misrepresent the true identity of an insurer.

b. No advertisement shall use any combination of words, symbols, or physical materials which by its content, phraseology, shape, color or other characteristics is so similar to combinations of words, symbols, or physical materials used by a municipal, state or federal agency that it would lead a reasonable individual to believe that the advertisement is approved, endorsed or accredited by an agency of the municipal, state, or federal government.

15.3(10) Disclosure requirements for life insurance and annuities.

a. An advertisement for a policy containing graded or modified benefits shall prominently display any limitation of benefits. If the premium is level and coverage decreases or increases with age or duration, such fact shall be prominently disclosed.

b. An advertisement for a policy with nonlevel premiums shall prominently describe the premium changes.

c. Dividends.

(1) An advertisement shall not state or imply that the payment or amount of dividends is guaranteed. If dividends for an annuity are illustrated, the illustration must be based on the insurer's illustrated scale and must contain a statement that the illustration is not to be construed as a guarantee or estimate of dividends to be paid in the future.

(2) An advertisement shall not state or imply that the illustrated scale under a participating policy or pure endowments will be or can be sufficient at any future time to ensure, without the further payment of premiums, the receipt of benefits, such as a paid-up policy, unless the advertisement clearly and precisely explains (1) what benefits or coverage would be provided at such time and (2) under what conditions this would occur.

d. An advertisement of a deferred annuity shall not state the net premium accumulation interest rate unless it discloses in close proximity thereto and with equal prominence the actual relationship between the gross and net premiums.

e. An advertisement that states the projected values of a policy must use the guaranteed interest rates in determining such projected values and, in addition, may show other projected values based on interest rates which comply with the illustrated scale. Any statements containing or based upon an interest rate higher than the guaranteed accumulation interest rates shall likewise set forth with equal prominence comparable statements containing or based upon the guaranteed accumulation interest rates. If the policy does not contain a provision for a guaranteed interest rate, any advertisement showing projected values must clearly state that the rates are not guaranteed. This subrule does not apply to an illustration or supplemental illustration subject to the provisions of the Life Illustrations Model Regulation, 191 IAC 14.

f. An advertisement or presentation which does not recognize the time value of money through the use of appropriate interest adjustments shall not be used for comparing the cost of two or more life insurance policies. Such advertisement may be used for the purpose of demonstrating the cash flow pattern of a policy if such advertisement is accompanied by a statement disclosing that the advertisement does not recognize that, because of interest, a dollar in the future may not have the same value as a dollar at the time of the presentation.

g. An advertisement of benefits shall not display guaranteed and nonguaranteed benefits as a single sum unless they are also shown separately in close proximity thereto.

h. A statement regarding the use of life insurance cost indexes shall include an explanation that the indexes are useful only for the comparison of the relative costs of two or more similar policies.

i. A life insurance cost index which reflects dividends or an equivalent level annual dividend shall be accompanied by a statement that it is based on the insurer's illustrated scale and is not guaranteed.

15.3(11) *Special offers.* Advertisements, applications, requests for additional information and similar materials are prohibited if they state or imply that the recipient has been individually selected to be offered insurance or has had the recipient's eligibility for the insurance individually determined in advance when the advertisement is directed to all individuals in a group or to all individuals whose names appear on a mailing list.

15.3(12) *Disclosure requirement.* In an advertisement that is an invitation to contract for an accident and sickness insurance policy that is guaranteed renewable, cancelable or renewable at the option of the company, the advertisement shall disclose that the insurer has the right to increase premium rates if the policy so provides.

15.3(13) *Group or quasi-group implications.*

a. An advertisement of a particular policy shall not state or imply that prospective insureds become group or quasi-group members covered under a group policy and, as members, enjoy special rates or underwriting privileges, unless that is the fact.

b. This rule prohibits the solicitation of a particular class, such as governmental employees, by use of advertisements which state or imply that their class membership entitles the member to reduced rates on a group or other basis when, in fact, the policy being advertised is sold only on an individual basis at regular rates.

c. Advertisements that indicate that a particular coverage or policy is exclusively for "preferred risks" or a particular segment of the population or that a particular segment of the population is an acceptable risk, when the distinctions are not maintained in the issuance of policies, are prohibited.

d. An advertisement to join an association, trust or discretionary group that is also an invitation to contract for insurance coverage shall clearly disclose that the applicant will be purchasing both membership in the association, trust or discretionary group and insurance coverage. The insurer shall solicit insurance coverage on a separate and distinct application that requires a separate signature. The separate and distinct application required need not be on a separate document or contained in a separate mailing. The insurance program shall be presented so as not to conceal the fact that the prospective members are purchasing insurance as well as applying for membership, if that is the case. Similarly,

the use of terms such as “enroll” or “join” to imply group or blanket insurance coverage is prohibited when that is not the fact.

e. Advertisements for group or franchise group plans that provide a common benefit or a common combination of benefits shall not imply that the insurance coverage is tailored or designed specifically for that group, unless that is the fact.

15.3(14) Compliance with Medicare supplement advertising rules. Insurers and producers shall comply with the Medicare supplement advertising rules set forth in 191—Chapter 37, Division II. [ARC 7964B, IAB 7/15/09, effective 8/19/09]

191—15.4(507B) Life insurance cost and benefit disclosure requirements.

15.4(1) The definition of terms applicable to this rule and its appendices will be found in Appendix I.

15.4(2) Except as hereafter exempted, this rule shall apply to any solicitation, negotiation or procurement of life insurance occurring within this state. This rule shall apply to any insurer issuing life insurance contracts including fraternal benefit societies.

Unless otherwise specifically included, this rule shall not apply to:

- a.* Annuities.
- b.* Credit life insurance.
- c.* Group life insurance, except for disclosures relating to preneed funeral contracts or prearrangements as provided herein. These disclosure requirements shall extend to the issuance or delivery of certificates as well as to the master policy.
- d.* Life insurance policies issued in connection with pension and welfare plans as defined by and which are subject to the federal Employee Retirement Income Security Act of 1974 (ERISA).
- e.* Variable life insurance under which the death benefits and cash values vary in accordance with unit values of investments held in a separate account.

15.4(3) Prior to or at delivery of a life insurance policy, an insurer or producer shall provide the prospective purchaser the following:

- a.* A life insurance buyer’s guide in the current form prescribed by the National Association of Insurance Commissioners or language approved by the commissioner of insurance, and
- b.* A policy summary as defined in Appendix I.

15.4(4) A policy summary is not required to include information available in the policy form or illustration. If an illustration subject to the provisions of 191 IAC 14, Life Insurance Illustrations Model Regulation, is used in the sale of a policy, delivery of a policy summary is not required. A policy summary may not include any element that is not guaranteed.

191—15.5(507B) Health insurance sales to individuals 65 years of age or older. The sale of duplicate Medicare supplement insurance is prohibited.

191—15.6(507B) Preneed funeral contracts or prearrangements. Rescinded ARC 2258C, IAB 11/25/15, effective 12/30/15.

191—15.7(507B) Twisting prohibited. No insurer or producer shall engage in the act of twisting.

191—15.8(507B) Producer responsibilities.

15.8(1) Required disclosures. A producer shall inform the prospective purchaser, prior to commencing an insurance sales presentation, that the producer is acting as an insurance producer and inform the prospective purchaser of the producer’s full name and the full name of the insurance company which the producer will represent in the insurance sales presentation. In sales situations in which a producer is not involved, the insurer shall identify its full name to a prospective purchaser.

15.8(2) Improper sales tactics.

- a.* Producers and insurers shall not employ any method of marketing or tactic which uses undue pressure, force, fright, threat, whether explicit or implied, to solicit the purchase of insurance.
- b.* A producer shall not:

(1) Execute a transaction for an insurance customer without authorization by the customer to do so; or

(2) Commit any act which shows that the producer has exerted undue influence over a person.

c. Producers and insurers shall not, without good cause:

(1) Fail or refuse to furnish any individual, upon reasonable request, information to which that individual is entitled, or to respond to a formal written request or complaint from any individual.

(2) Sell an insurance policy or rider to an individual which is a duplication of a policy or rider which the individual owns or for which the individual has applied at the time of the sale.

15.8(3) Prohibited designations and fees.

a. When an insurance producer is engaged only in the sale of insurance policies or annuities, the insurance producer shall not hold the producer out, directly or indirectly, to the public as a “financial planner,” “investment adviser,” “consultant,” “financial counselor,” or any other specialist solely engaged in the business of financial planning or giving advice relating to investments, insurance, real estate, tax matters or trust and estate matters. This provision does not preclude insurance producers who hold some form of formal recognized financial planning or consultant certification or designation from using this certification or designation when they are only selling insurance.

b. An insurance producer shall not engage in the business of financial planning without disclosing to the client prior to the execution of the agreement required by paragraph “c” or to the solicitation of the sale of a product or service that the producer is also an insurance producer and that a commission for the sale of an insurance product will be received in addition to a fee for financial planning, if such is the case. The disclosure requirement under this paragraph may be met by including the disclosure in any disclosure required by federal or state securities law.

c. An insurance producer shall not charge fees other than commissions unless such fees are based upon a written agreement signed by the client in advance of the performance of the services under the agreement. A copy of the agreement must be provided to the client at the time the agreement is signed by the client. The agreement must specifically state:

(1) The service for which the fee is to be charged;

(2) The amount of the fee to be charged or how it will be determined or calculated; and

(3) That the client is under no obligation to purchase any insurance product through the insurance producer or consultant.

The insurance producer shall retain a copy of the agreement for not less than three years after completion of services, and a copy shall be available to the commissioner upon request.

d. Producers shall not charge an additional fee for services that are customarily associated with the solicitation, negotiation or servicing of policies. This prohibition shall not apply to assigned risk policies and commercial property and casualty policies. Any additional fee that a producer intends to charge for assigned risk policies and commercial property and casualty policies must be fully disclosed to the insured.

e. Producers shall comply with rule 191—10.19(522B) in using senior-specific certifications and professional designations in the sale of life insurance and annuities.

15.8(4) Suitability. A producer shall not recommend to any person the purchase, sale or exchange of any life insurance policy, or any rider, endorsement or amendment thereto, without reasonable grounds to believe that the transaction or recommendation is not unsuitable for the person based upon reasonable inquiry concerning the person’s insurance objectives, financial situation and needs, age and other relevant information known by the producer. For purposes of this subrule, when a producer recommends a group life insurance policy, “person” shall refer to the intended group policyowner.

15.8(5) Prohibited acts.

a. For purposes of this subrule:

“Gift” means a rendering of anything of value in return for which legal consideration of equal or greater value is not given and received.

“Immediate family” shall include parent, mother-in-law, father-in-law, spouse, former spouse, brother, sister, brother-in-law, sister-in-law, son-in-law, daughter-in-law, child and stepchild. In

addition, “immediate family” shall include any other person who is supported, directly or indirectly, to a material extent by a producer.

“*Loan*” means an agreement to advance property, including but not limited to money, in return for the promise that payment will be made for use of the property.

b. A producer shall not:

(1) Solicit or accept, directly or indirectly, at any time, a personal loan from an insurance customer that in the aggregate exceeds \$250, unless the customer is:

1. A bank, savings and loan, credit union or other recognized lending entity; or
2. A member of the producer’s immediate family.

(2) Solicit or accept, directly or indirectly, at any time, a gift to the producer or to a member of the producer’s immediate family from an insurance customer that in the aggregate exceeds \$250, unless the customer is a member of the producer’s immediate family. A gift to a member of the producer’s immediate family shall be included in calculating the aggregate amount. A gift received by a member of the producer’s immediate family from a customer that is not a member of the producer’s immediate family in excess of the aggregate amount shall be deemed a violation of this subrule by the producer.

(3) Solicit or accept being named as a beneficiary, executor or trustee in a will, trust, insurance policy or annuity of a customer, unless the customer is a member of the producer’s immediate family.

(4) Evade or otherwise violate the spirit of this subrule by terminating a producer relationship with an insurance customer for the purpose of soliciting or accepting a loan or a gift, or for the purpose of being named as a beneficiary, executor or trustee in a will, trust, insurance policy or annuity that the producer otherwise would have been prohibited from soliciting or accepting by this subrule. A producer will not be in violation of this subrule if the producer has made a bona fide termination of the producer relationship with the insurance customer and has conducted no insurance or other business with the insurance customer for a period of three years.

c. Transactions which involve nominal interim ownership immediately precedent to transfer of ownership into a trust are exempt from this subrule.

191—15.9(507B) Right to return a life insurance policy or annuity (free look). The owner of an individual policy has the right, within ten days after receipt of a life insurance policy or annuity, to a free-look period. During this period, the policyowner may return the life insurance policy or annuity to the insurer at its home office, branch office, or to the producer through whom it was purchased. If so returned, the premium paid will be promptly refunded, the policy or annuity voided and the parties returned to the same position as if a policy or annuity had not been issued. If the transaction involved a replacement, the length of the free-look period will be determined according to 191—Chapter 16.

If the transaction involved a variable product, the amount to be refunded shall be determined according to the policy language. The calculations must comply with the relevant rule in either 191—Chapter 16, Replacement of Life Insurance and Annuities, or 191—Chapter 33, Variable Life Insurance Model Regulation.

191—15.10(507B) Uninsured/underinsured automobile coverage—notice required.

15.10(1) Contents of notice. Automobile insurance policies delivered in this state shall include a notice which contains and is limited to the following language:

NOTICE REGARDING UNINSURED/UNDERINSURED COVERAGE

Uninsured/underinsured coverage does not cover damage done to your vehicle. It provides benefits only for bodily injury caused by an uninsured or underinsured motorist. If you wish to be insured for damage done to your vehicle, you must have collision coverage. Please check your policy to make sure you have the coverage desired.

15.10(2) Form of notice. Notice may be provided on a separate form or may be stamped on the declaration page of the policy. The notice shall be provided in conjunction with all new policies issued. Notice may be provided at the time of application but shall in no case be provided later than the time of delivery of the new policy. Insurers may inform applicants that the notice in this rule is required by the insurance division.

191—15.11(507B) Unfair discrimination.**15.11(1) Sex discrimination.**

a. A contract shall not be denied to an individual based solely on that individual's sex or marital status. No benefits, terms, conditions or type of coverage shall be restricted, modified, excluded, or reduced on the basis of the sex or marital status of the insured or prospective insured except to the extent permitted under the Iowa Code or Iowa Administrative Code. An insurer may consider marital status for the purpose of defining individuals eligible for dependents' benefits. This subrule does not apply to group life insurance policies or group annuity contracts issued in connection with pension and welfare plans which are subject to the federal Employee Retirement Income Security Act of 1974 (ERISA).

b. Specific examples of practices prohibited by this subrule include, but are not limited to, the following:

(1) Denying coverage to individuals of one sex employed at home, employed part-time or employed by relatives when coverage is offered to individuals of the opposite sex similarly employed.

(2) Denying policy riders to persons of one sex when the riders are available to persons of the opposite sex.

(3) Denying a policy under which maternity coverage is available to an unmarried female when that same policy is available to a married female.

(4) Denying, under group contracts, dependent coverage to spouses of employees of one sex, when dependent coverage is available to spouses of employees of the opposite sex.

(5) Denying disability income coverage to employed members of one sex when coverage is offered to members of the opposite sex similarly employed.

(6) Treating complications of pregnancy differently from any other illness or sickness under the contract.

(7) Restricting, reducing, modifying, or excluding benefits relating to coverage involving the genital organs of only one sex.

(8) Offering lower maximum monthly benefits to members of one sex than to members of the opposite sex who are in the same underwriting and occupational classification under a disability income contract.

(9) Offering more restrictive benefit periods and more restrictive definitions of disability to members of one sex than to members of the opposite sex in the same underwriting and occupational classifications under a disability income contract.

(10) Establishing different contract conditions based on gender which limit the benefit options a policyholder may exercise.

(11) Limiting the amount of coverage due to an insured's or prospective insured's marital status unless such limitation applies only to coverage for dependents and is uniformly applied to males and females.

c. When rates are differentiated on the basis of sex, an insurer must, upon the request of the commissioner of insurance, justify the rate differential in writing to the satisfaction of the commissioner. All rates shall be based on sound actuarial principles or a valid classification system and actual experience statistics, if available.

d. This subrule shall not affect the right of fraternal benefit societies to determine eligibility requirements for membership. If a fraternal benefit society does, however, admit members of both sexes, this subrule is applicable to the insurance benefits available to its members.

15.11(2) Physical or mental impairment. No contract, benefits, terms, conditions or type of coverage shall be denied, restricted, modified, excluded or reduced solely on the basis of physical or mental impairment of the insured or prospective insured except where based on sound actuarial principles or related to actual or reasonably anticipated experience. For purposes of this subrule, both blindness and partial blindness shall be considered a physical impairment.

15.11(3) Income discrimination. An insurer shall not refuse to issue, limit the amount or apply different rates to individuals of the same class in the sale of individual life insurance based solely upon the prospective insured's legal source or level of income, unless such action is based on sound actuarial

principles or is related to actual or reasonably anticipated experience. The portion of this subrule pertaining to level of income does not:

- a. Apply to the sale of disability income insurance of any kind or of any insurance designed to protect against economic loss due to a disruption in the regular flow of an individual's earned income;
- b. Prohibit the sale of any insurance or annuity which is made available only to employees;
- c. Prohibit basing the amount of insurance sold to an employee on a multiple or a percentage of the employee's salary or prohibit limiting availability to employees who have achieved a certain employment status as defined by the employer;
- d. Prohibit insurers from providing life or health insurance as an incidental benefit through a qualified pension plan;
- e. Prohibit insurers from applying suitability standards which include income as a factor in the sale of any life insurance or annuity products;
- f. Prohibit insurers from establishing maximum or minimum amounts of insurance that will be issued to individuals so long as this is pursuant to a preexisting specialized marketing strategy which the insurer can demonstrate is related to the financial capacity of the insurer to write business or to bona fide transaction costs.

15.11(4) Domestic abuse. A contract shall not be denied to an individual based solely on the fact that such individual has been or is believed to have been a victim of domestic abuse as defined in Iowa Code section 236.2.

15.11(5) Genetic information. Any action by an insurer that is not in compliance with Title I of the Genetic Information Nondiscrimination Act of 2008 (Public Law 110-233, 122 Stat. 881) shall be considered an unfair trade practice and shall be subject to the penalties of Iowa Code chapter 507B and of these rules.

15.11(6) Discrimination relating to children under the age of 19. It is an unfair trade practice to:

- a. Encourage individuals or groups to refrain from filing an application with an insurer for coverage for a child under the age of 19 because of the child's health status, claims experience, industry, occupation, or geographic location;
- b. Encourage or direct children under the age of 19 to seek coverage from another insurer because of the child's health status, claims experience, industry, occupation, or geographic location; and
- c. Encourage an employer to exclude an employee from coverage.

[ARC 7796B, IAB 5/20/09, effective 5/22/09; ARC 7965B, IAB 7/15/09, effective 8/19/09; ARC 9498B, IAB 5/4/11, effective 6/8/11]

191—15.12(507B) Testing restrictions of insurance applications for the human immunodeficiency virus.

15.12(1) Written release. No insurer shall obtain a test of any individual in connection with an application for insurance for the presence of an antibody to the human immunodeficiency virus unless the individual to be tested provides a written release on a form which contains the following information:

- a. A statement of the purpose, content, use, and meaning of the test.
- b. A statement regarding disclosure of the test results including information explaining the effect of releasing the information to an insurer.
- c. A statement of the purpose for which test results may be used.

15.12(2) Form. A preapproved form is provided in Appendix II. An insurer wishing to utilize a form which deviates from the language in the appendix to these rules shall submit the form to the insurance division for approval. Any form containing, but not limited to, the language in the appendix shall be deemed approved.

15.12(3) Test results. A person engaged in the business of insurance who receives results of a positive human immunodeficiency virus (HIV) test in connection with an application for insurance shall report those results to a physician or alternative testing site of the applicant's or policyholder's choice or, if the applicant or policyholder does not choose a physician or alternative testing site to receive the results, to the Iowa department of public health.

191—15.13(507B) Records maintenance.

15.13(1) *Complaint and business records.*

a. An insurer shall maintain its books, records, documents and other business records in such an order that data regarding complaints, claims, rating, underwriting and marketing are accessible and retrievable for examination by the insurance commissioner.

b. An insurer shall maintain a complete record of all the complaints received since the date of its last examination by the insurer's state of domicile or port-of-entry state. This record shall indicate the total number of complaints, their classification by line of insurance, the nature of each complaint, the disposition of each complaint, and the time it took to process each complaint. Appendix IV sets forth the minimum information required to be contained in the complaint record.

15.13(2) *Insurer's control over advertisements.* Every insurer shall establish and at all times maintain a system of control over the content, form, and method of dissemination of all advertisements which explain a particular policy. All such advertisements, whether written, created, designed or presented by the insurer or its appointed producer, shall be the responsibility of the insurer whose particular policies are so advertised. As part of this requirement, each insurer shall maintain at its home or principal office a complete file containing a specimen copy of every printed, published or prepared advertisement of its policies, with a notation indicating the manner and extent of distribution and the form number of any policy advertised. Such file shall be subject to inspection by the insurance division. All such advertisements shall be maintained for a period of either four years or until the filing of the next regular report on examination of the insurer, whichever is the longer period of time.

15.13(3) *Education and training materials.* Every insurer shall establish and maintain a system of control over the content and form of all material used by the insurer or any of its employees for the recruitment, training, and education of producers in the sale of insurance. Upon request, copies of these materials shall be made available to the commissioner.

191—15.14(505,507B) Enforcement section—cease and desist and penalty orders.

15.14(1) If, after hearing, the commissioner determines that a person has engaged in an unfair trade practice in violation of these rules, an unfair method of competition, or an unfair or deceptive act or practice in violation of Iowa Code chapter 507B, the commissioner shall reduce the findings to writing and shall issue and cause to be served upon the person charged with the violation a copy of such findings and an order requiring the person to cease and desist from engaging in such method of competition, act or practice. The commissioner also may order one or more of the following:

a. Payment of a civil penalty of not more than \$1,000 for each act or violation, but not to exceed an aggregate penalty of \$10,000, unless the person knew or reasonably should have known that the actions were in violation of these rules or of Iowa Code chapter 507B, in which case the penalty shall be not more than \$5,000 for each act or violation, but not to exceed an aggregate penalty of \$50,000 in any one six-month period. If the commissioner finds that a violation of these rules or of Iowa Code chapter 507B was directed, encouraged, condoned, ignored, or ratified by the employer of the person or by an insurer, the commissioner shall also assess a fine to the employer or insurer;

b. Suspension or revocation of an insurer's certificate of authority or the producer's license if the insurer or producer knew or reasonably should have known that it was in violation of these rules or of Iowa Code chapter 507B;

c. Payment of interest at the rate of 10 percent per annum if the commissioner finds that the insurer failed to pay interest as required under Iowa Code section 507B.4, subsection 12;

d. Full disclosure by the insurer of all terms and conditions of the policy to the policyowner;

e. Payment of the costs of the investigation and administrative expenses related to any act or violation. The commissioner may retain funds collected pursuant to any settlement, enforcement action, or other legal action authorized under federal or state law for the purpose of reimbursing costs and expenses of the division.

15.14(2) Any person who violates a cease and desist order of the commissioner while such order is in effect may, after notice and hearing and upon order of the commissioner, be subject at the discretion of the commissioner to one or both of the following:

a. A civil penalty of not more than \$10,000 for each and every act or violation.

- b. Suspension or revocation of such person's license.

191—15.15 to 15.30 Reserved.

DIVISION II
CLAIMS

191—15.31(507B) General claims settlement guidelines. No insurer shall issue checks or drafts in partial settlement of a loss or claim under a specific coverage that contains language purporting to release the insurer or its insured from total liability.

191—15.32(507B) Prompt payment of certain health claims. Effective July 1, 2002, the following provisions apply:

15.32(1) Definitions and scope.

- a. For purposes of this rule, the following definitions apply:

"Circumstance requiring special treatment" means:

1. A claim that an insurer has a reasonable basis to suspect may be fraudulent or that fraud or a material misrepresentation may have occurred under the benefit certificate or policy or in obtaining such certificate or policy; or
2. A matter beyond the insurer's control, such as an act of God, insurrection, strike or other similar labor dispute, fire or power outage or, for a group-sponsored health plan, the failure of the sponsoring group to pay premiums to the insurer in a timely manner; or
3. Similar unique or special circumstances which would reasonably prevent an insurer from paying an otherwise clean claim within 30 days.

"Clean claim" means clean claim as defined in 2001 Iowa Acts, chapter 69, section 8(2b).

"Coordination of benefits for third-party liability" means a claim for benefits by a covered individual who has coverage under more than one health benefit plan.

"Insurer" means insurer as defined in 2001 Iowa Acts, chapter 69, section 7.

"Properly completed billing instrument" means:

1. In the case of a health care provider that is not a health care professional:
 - The Health Care Finance Administration (HCFA) Form 1450, also known as Form UB-92, or similar form adopted by its successor Centers for Medicare/Medicaid Services (CMS) as adopted by the National Uniform Billing Committee (NUBC) with data element usage prescribed in the UB-92 National Uniform Billing Data Elements Specification Manual, or
 - The electronic format for institutional claims adopted as a standard by the Secretary of Health and Human Services pursuant to Section 1173 of the Social Security Act; or
2. In the case of a health care provider that is a health care professional:
 - The HCFA Form 1500 paper form or its successor as adopted by the National Uniform Claim Committee (NUCC) and further defined by the NUCC in its implementation guide; or
 - The electronic format for professional claims adopted as a standard by the Secretary of Health and Human Services pursuant to Section 1173 of the Social Security Act; and
3. Any other information reasonably necessary for an insurer to process a claim for benefits under the benefit certificate or policy with the insured contract.

b. Scope. This subrule applies to claims submitted to an insurer as defined above on or after July 1, 2002, and is limited to policies issued, issued for delivery, or renewed in this state.

15.32(2) Insurer duty to promptly pay claims and pay interest.

a. Insurers subject to this subrule shall either accept and pay or deny a clean claim for health care benefits under a benefit certificate or policy issued by the insurer within 30 days after the insurer's receipt of such claim. A clean claim is considered to be paid on the date upon which a check, draft, or other valid negotiable instrument is written. Insurers shall implement procedures to ensure that these payments are promptly delivered.

b. Insurers or entities that administer or process claims on behalf of an insurer who fail to pay a clean claim within 30 days after the insurer's receipt of a properly completed billing instrument shall

pay interest. Interest shall accrue at the rate of 10 percent per annum commencing on the thirty-first day after the insurer's receipt of all information necessary to establish a clean claim. Interest will be paid to the claimant or provider based upon who is entitled to the benefit payment.

c. Insurers shall have 30 days from the receipt of a claim to request additional information to establish a clean claim. An insurer shall provide a written or electronic notice to the claimant or health care provider if additional information is needed to establish a clean claim. The notice shall include a full explanation of the information necessary to establish a clean claim.

d. Effective January 1, 2003, when a claim involves coordination of benefits, an insurer is required to comply with the requirements of this subrule when that insurer's liability has been determined.

15.32(3) *Certain insurance products exempt.* Claims paid under the following insurance products are exempt from the provisions of this subrule: liability insurance, workers' compensation or similar insurance, automobile or homeowners insurance, medical payment insurance or disability income insurance.

This rule is intended to implement Iowa Code sections 507B.4A and 514G.111 and 2015 Iowa Acts, House File 632, section 21.

[ARC 2296C, IAB 12/9/15, effective 1/13/16]

191—15.33(507B) Audit procedures for medical claims.

15.33(1) *Prohibitions.* This rule applies to all claims paid on or after January 1, 2002:

a. Absent a reasonable basis to suspect fraud, an insurer may not audit a claim more than two years after the submission of the claim to the insurer. Nothing in this rule prohibits an insurer from requesting all records associated with the claim.

b. Absent a reasonable basis to suspect fraud, an insurer may not audit a claim with a billed charge of less than \$25.

15.33(2) *Standards.*

a. In auditing a claim, the insurer must make a reasonable effort to ensure that the audit is performed by a person or persons with appropriate qualifications for the type of audit being performed.

b. In auditing a claim, the auditor must use the coding guidelines and instructions that were in effect on the date the medical service was provided.

15.33(3) *Contents of audit request.* All correspondence regarding the audit of a claim must include the following information:

a. The name, address, telephone number and contact person of the insurer conducting the audit,

b. The name of the entity performing the audit if not the insurer,

c. The purpose of the audit, and

d. If included in the audit, the specific coding or billing procedure that is under review.

This rule is intended to implement Iowa Code section 507B.4, subsection 9, as amended by 2001 Iowa Acts, chapter 69.

191—15.34 to 15.40 Reserved.

191—15.41(507B) Claims settlement guidelines for property and casualty insurance. For purposes of this rule, "insurer" means property and casualty insurers.

15.41(1) An insurer shall fully disclose to first-party claimants all pertinent benefits, coverages or other provisions of a policy or contract under which a claim is presented.

15.41(2) Within 30 days after receipt by the insurer of properly executed proofs of loss, the first-party property claimant shall be advised of the acceptance or denial of the claim by the insurer. No insurer shall deny a claim on the grounds of a specific policy provision, condition or exclusion unless reference to such provision, condition, or exclusion is included in the denial. The denial must be given to the claimant in writing, and the claim file of the insurer shall contain documentation of the denial.

When there is a reasonable basis supported by specific information available for review by the commissioner that the first-party claimant has fraudulently caused or contributed to the loss, the insurer is relieved from the requirements of this subrule. However, the claimant shall be advised of the acceptance

or denial of the claim within a reasonable time for full investigation after receipt by the insurer of a properly executed proof of loss.

15.41(3) If the insurer needs more time to determine whether a first-party claim should be accepted or denied, the insurer shall so notify the first-party claimant within 30 days after receipt of the proof of loss and give the reasons more time is needed. If the investigation remains incomplete, the insurer shall, 45 days from the initial notification and every 45 days thereafter, send to the claimant a letter setting forth the reasons additional time is needed for investigation.

When there is a reasonable basis supported by specific information available for review by the commissioner for suspecting that the first-party claimant has fraudulently caused or contributed to the loss, the insurer is relieved from the requirements of this subrule. However, the claimant shall be advised of the acceptance or denial of the claim by the insurer within a reasonable time for full investigation after receipt by the insurer of a properly executed proof of loss.

15.41(4) Insurers shall not fail to settle first-party claims on the basis that responsibility for payment should be assumed by others except as may otherwise be provided by policy provisions.

15.41(5) No insurer shall make statements indicating that the rights of a third-party claimant may be impaired if a form or release, other than a release to obtain medical records, is not completed within a given period of time unless the statement is given for the purpose of notifying the third-party claimant of the provision of a statute of limitations.

15.41(6) The insurer shall affirm or deny liability on claims within a reasonable time and shall tender payment within 30 days of affirmation of liability, if the amount of the claim is determined and not in dispute. In claims where multiple coverages are involved, payments which are not in dispute under one of the coverages and where the payee is known should be tendered within 30 days if such payment would terminate the insurer's known liability under that coverage.

15.41(7) No producer shall conceal from a first-party claimant benefits, coverages or other provisions of any insurance policy or insurance contract when such benefits, coverages or other provisions are pertinent to a claim.

15.41(8) A claim shall not be denied on the basis of failure to exhibit property unless there is documentation of breach of the policy provisions to exhibit or cooperate in the claim investigation.

15.41(9) No insurer shall deny a claim based upon the failure of a first-party claimant to give written notice of loss within a specified time limit unless the written notice is a written policy condition. An insurer may deny a claim if the claimant's failure to give written notice after being requested to do so is so unreasonable as to constitute a breach of the claimant's duty to cooperate with the insurer.

15.41(10) No insurer shall indicate to a first-party claimant on a payment draft, check or in any accompanying letter that said payment is "final" or "a release" of any claim unless the policy limit has been paid or there has been a compromise settlement agreed to by the first-party claimant and the insurer as to coverage and amount payable under the contract.

15.41(11) No insurer shall request or require any insured to submit to a polygraph examination unless authorized under the applicable insurance contracts and state law.

191—15.42(507B) Acknowledgment of communications by property and casualty insurers. For purposes of this rule, "insurer" means property and casualty insurers.

15.42(1) Upon receiving notification of a claim, an insurer shall, within 15 days, acknowledge the receipt of such notice unless payment is made within that period of time. If an acknowledgment is made by means other than in writing, an appropriate notation of the acknowledgment shall be made in the claim file of the insurer and dated.

15.42(2) Upon receipt of any inquiry from the Iowa insurance division regarding a claim, an insurer shall, within 21 days of receipt of such inquiry, furnish the division with an adequate response to the inquiry, in duplicate.

15.42(3) The insurer shall reply within 15 days to all pertinent communications from a claimant which reasonably suggest that a response is expected.

15.42(4) Upon receiving notification of claim, an insurer shall promptly provide necessary claim forms, instructions and reasonable assistance so that first-party claimants can comply with the policy

conditions and the insurer's reasonable requirements. Compliance with this subrule within 15 days of notification of a claim shall constitute compliance with subrule 15.42(1).

191—15.43(507B) Standards for settlement of automobile insurance claims.

15.43(1) Loss calculation and deviation guidelines.

a. Loss calculation. When the insurance policy provides for the adjustment and settlement of first-party automobile total losses on the basis of actual cash value or replacement with another automobile of like kind and quality, one of the following methods shall apply:

(1) The insurer may elect to offer a replacement automobile that is at least comparable in that it will be by the same manufacturer, same or newer year, similar body style, similar options and mileage as the insured vehicle and in as good or better overall condition and available for inspection at a licensed dealer within a reasonable distance of the insured's residence. All applicable taxes, license fees and other fees incident to the transfer of evidence of ownership of the automobile shall be paid by the insurer, at no cost to the insured, other than any deductible provided in the policy. The offer and any rejection thereof must be documented in the claim file.

(2) The insurer may elect a cash settlement based upon the actual cost, less any deductible provided in the policy, to purchase a comparable automobile including all applicable taxes, license fees and other fees incident to transfer of evidence of ownership of a comparable automobile. Such cost may be derived from:

1. The cost of two or more comparable automobiles in the local market area when comparable automobiles are available or were available within the last 90 days to consumers in the local market area; or

2. The cost of two or more comparable automobiles in areas proximate to the local market area, including the closest major metropolitan areas within or without the state, that are available or were available within the last 90 days to consumers when comparable automobiles are not available in the local market area; or

3. One of two or more quotations obtained by the insurer from two or more licensed dealers located within the local market area when the cost of comparable automobiles is not available; or

4. Any source for determining statistically valid fair market values that meet all of the following criteria:

- The source shall give primary consideration to the values of vehicles in the local market area and may consider data on vehicles outside the area.
- The source's database shall produce values for at least 85 percent of all makes and models for the last 15 model years taking into account the values of all major options for such vehicles.
- The source shall produce fair market values based on current data available from the area surrounding the location where the insured vehicle was principally garaged or a necessary expansion of parameters (such as time and area) to ensure statistical validity.

(3) If the insurer is notified within 35 days of the receipt of the claim draft that the insured cannot purchase a comparable vehicle for such market value, the insured shall have a right of recourse. The insurer shall reopen its claim file and the following procedure(s) shall apply:

1. The insurer may locate a comparable vehicle by the same manufacturer, same or newer year, similar body style and similar options and price range for the insured for the market value determined by the insurer at the time of settlement. Any such vehicle must be available through a licensed dealer; or

2. The insurer shall either pay the insured the difference between the market value before applicable deductions and the cost of the comparable vehicle of like kind and quality which the insured has located, or negotiate and effect the purchase of this vehicle for the insured; or

3. The insurer may elect to offer a replacement in accordance with the provisions set forth in subrule 15.43(1); or

4. The insurer may conclude the loss settlement as provided for under the appraisal section of the insurance contract in force at the time of loss. This appraisal shall be considered as binding against both parties, but shall not preclude or waive any other rights either party has under the insurance contract or a common law.

The insurer is not required to take action under this subrule if its documentation to the insured at the time of settlement included written notification of the availability and location of a specified and comparable vehicle of the same manufacturer, same or newer year, similar body style and similar options in as good or better condition as the total-loss vehicle which could have been purchased for the market value determined by the insurer before applicable deductions. The documentation shall include the vehicle identification number.

b. Deviation. When a first-party automobile total loss is settled on a basis which deviates from the methods described in paragraph “a,” the deviation must be supported by documentation giving particulars of the automobile’s condition. Any deductions from such cost, including deduction for salvage, must be measurable, discernible, itemized and specified as to dollar amount and shall be appropriate in amount. The basis for such settlement shall be fully explained to the first-party claimant.

15.43(2) Where liability and damages are reasonably clear, an insurer shall not recommend that third-party claimants make claims under their own policies solely to avoid paying claims under the insurer’s policy.

15.43(3) The insurer shall not require a claimant to travel an unreasonable distance either to inspect a replacement automobile, to obtain a repair estimate or to have the automobile repaired at a specific repair shop.

15.43(4) The insurer shall, upon the claimant’s request, include the first-party claimant’s deductible, if any, in subrogation demands. Subrogation recoveries shall be shared on a proportionate basis with the first-party claimant, unless the deductible amount has been otherwise recovered. No deduction for expenses shall be made from the deductible recovery unless an outside attorney is retained to collect such recovery. The deduction may then be for only a pro-rata share of the allocated loss adjustment expense.

15.43(5) Vehicle repairs. If partial losses are settled on the basis of a written estimate prepared by or for the insurer, the insurer shall supply the insured a copy of the estimate upon which the settlement is based. The estimate prepared by or for the insurer shall be reasonable, in accordance with applicable policy provisions, and of an amount which will allow for repairs to be made in a workmanlike manner. If the insured subsequently claims, based upon a written estimate which the insured obtains, that necessary repairs will exceed the written estimate prepared by or for the insurer, the insurer shall (1) pay the difference between the written estimate and a higher estimate obtained by the insured, or (2) promptly provide the insured with the name of at least one repair shop that will make the repairs for the amount of the written estimate. If the insurer designates only one or two such repair shops, the insurer shall ensure that the repairs are performed according to automobile industry standards. The insurer shall maintain documentation of all such communications.

15.43(6) When the amount claimed is reduced because of betterment or depreciation, all information for such reduction shall be contained in the claim file. Such deductions shall be itemized and specified as to dollar amount and shall be appropriate for the amount of deductions.

15.43(7) When the insurer elects to repair an automobile, the insurer shall cause the damaged automobile to be restored to its condition prior to the loss at no additional cost to the claimant other than as stated in the policy, within a reasonable period of time.

15.43(8) Storage and towing. The insurer shall provide reasonable notice to an insured prior to termination of payment for automobile storage charges. The insurer shall provide reasonable time for the insured to remove the vehicle from storage prior to the termination of payment. Unless the insurer has provided an insured with the name of a specific towing company prior to the insured’s use of another towing company, the insurer shall pay all reasonable towing charges.

15.43(9) Betterment. Betterment deductions are allowable only if the deductions reflect a measurable decrease in market value attributable to the poorer condition of, or prior damage to, the vehicle. Betterment deductions must be measurable, itemized, specified as to dollar amount and documented in the claim file.

15.43(10) Diminished value. Rescinded IAB 4/28/04, effective 4/7/04.

191—15.44(507B) Standards for determining replacement cost and actual cost values.

15.44(1) Replacement cost. When the policy provides for the adjustment and settlement of first-party losses based on replacement cost, the following shall apply:

a. When a loss requires repair or replacement of an item or part, any consequential physical damage incurred in making such repair or replacement not otherwise excluded by the policy shall be included in the loss. The insured shall not have to pay for betterment or any other cost except for the applicable deductible.

b. When a loss requires replacement of items and the replaced items do not match in quality, color or size, the insurer shall replace as much of the item as is necessary to result in a reasonably uniform appearance within the same line of sight. This subrule applies to interior and exterior losses. Exceptions may be made on a case-by-case basis. The insured shall not bear any cost over the applicable deductible, if any.

15.44(2) Actual cash value.

a. When the insurance policy provides for the adjustment and settlement of losses on an actual cash value basis on residential fire and extended coverage, the insurer shall determine the actual cash value. “Actual cash value” means replacement cost of property at time of loss, less depreciation, if any. Alternatively, an insurer may use market value in determining actual cash value. Upon the insured’s request, the insurer shall provide a copy of the claim file worksheet(s) detailing any and all deductions for depreciation.

b. In cases in which the insured’s interest is limited because the property has nominal or no economic value, or a value disproportionate to replacement cost less depreciation, the determination of actual cash value as set forth above is not required. In such cases, the insurer shall provide, upon the insured’s request, a written explanation of the basis for limiting the amount of recovery along with the amount payable under the policy.

15.44(3) Applicability. This rule does not apply to automobile insurance claims.

191—15.45(507B) Guidelines for use of aftermarket crash parts in motor vehicles.

15.45(1) Identification. All aftermarket crash parts supplied for use in this state shall comply with the identification requirements of Iowa Code section 537B.4.

15.45(2) Like kind and quality. An insurer shall not require the use of aftermarket crash parts in the repair of an automobile unless the aftermarket crash part is certified by a nationally recognized entity to be at least equal in kind and quality to the original equipment manufacturer part in terms of fit, quality and performance, or that the part complies with federal safety standards.

15.45(3) Contents of notice. Any automobile insurance policy delivered in this state that pays benefits based on the cost of aftermarket crash parts or that requires the insured to pay the difference between the cost of original equipment manufacturer parts and the cost of aftermarket crash parts shall include a notice which contains and is limited to the following language:

NOTICE—PAYMENT FOR AFTERMARKET CRASH PARTS

Physical damage coverage under this policy includes payment for aftermarket crash parts. If you repair the vehicle using more expensive original equipment manufacturer (OEM) parts, you may pay the difference. Any warranties applicable to these replacement parts are provided by the manufacturer or distributor of these parts rather than the manufacturer of your vehicle.

15.45(4) Form of notice. Notice may be provided on a separate form or may be printed prominently on the declaration page of the policy. The notice shall be provided in conjunction with all new policies issued. Notice may be provided at the time of application, but shall in no case be provided later than the time of delivery of the new policy. Insurers may inform applicants that the insurance division requires the notice in this rule.

191—15.46 to 15.50 Reserved.

DIVISION III
DISCLOSURE FOR SMALL FACE AMOUNT LIFE INSURANCE POLICIES

191—15.51(507B) Purpose. The purpose of these rules is to ensure the provision of meaningful information to the purchasers of small face amount life insurance policies. The rules in this division apply to all small face amount policies not exempted under rule 191—15.53(507B) that are issued on or after July 1, 2004.

191—15.52(507B) Definition. “*Small face amount policy*” means a life insurance policy or certificate with an initial face amount of \$15,000 or less.

191—15.53(507B) Exemptions. These rules apply to all group and individual life insurance policies and certificates except:

1. Variable life insurance;
2. Individual and group annuity contracts;
3. Credit life insurance;
4. Group or individual policies of life insurance issued to members of an employer group or other permitted group when:
 - Every plan of coverage was selected by the employer or other group representative;
 - Some portion of the premium is paid by the group or through payroll deduction; and
 - Group underwriting or simplified underwriting is used; and
5. Policies and certificates where an illustration has been provided pursuant to the requirements of 191—Chapter 14.

191—15.54(507B) Disclosure requirements.

15.54(1) An insurer issuing a small face amount policy shall provide the disclosure included in Appendix IV if at any point in time over the term of the policy the cumulative premiums paid may exceed the face amount of the policy at that point in time. The required disclosure shall be provided to the policy owner or certificate holder no later than at the time the policy or certificate is delivered. The disclosure shall not be attached to the policy, but may be delivered with the policy.

15.54(2) If, for a particular policy form, the cumulative premiums may exceed the face amount for some demographic or benefit combination but not for all combinations, the insurer may choose to either:

- a. Provide the disclosure only in those circumstances when the premiums may exceed the face amount; or
- b. Provide the disclosure for all demographic and benefit combinations.

15.54(3) Cumulative premiums shall include premiums paid for riders. However, the face amount shall not include the benefit attributable to the riders.

191—15.55(507B) Insurer duties. The insurer and its producers shall have a duty to provide information to policyholders or certificate holders that ask questions about the disclosure statement.

191—15.56 to 15.60 Reserved.

DIVISION IV
ANNUITY DISCLOSURE REQUIREMENTS

191—15.61(507B) Purpose. The purpose of the rules in Division IV of this chapter is to provide standards for the disclosure of certain minimum information about annuity contracts to protect consumers and to foster consumer education. The rules specify the minimum information which must be disclosed, the method for disclosing it and the use and content of illustrations, if used, in connection with the sale of annuity contracts. The goal of these rules is to ensure that purchasers of annuity contracts understand certain basic features of annuity contracts.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.62(507B) Applicability and scope. These rules apply to all annuities not exempted under this rule 191—15.62(507B) for which applications are taken on or after January 1, 2013, except that rule 191—15.66(507B) applies to all annuities not exempted under this rule 191—15.62(507B) which are in effect or for which applications are taken on or after January 1, 2013, and except that rule 191—15.67(507B) applies to all annuity contracts not exempted under this rule 191—15.62(507B) which are in effect on or after January 1, 2013. These rules apply to all group and individual annuity contracts and certificates except:

15.62(1) Immediate and deferred annuities that contain no nonguaranteed elements;

15.62(2) Annuities used to fund:

a. An employee pension plan which is covered by the Employee Retirement Income Security Act (ERISA);

b. A plan described by Section 401(a), 401(k) or 403(b) of the Internal Revenue Code, where the plan, for purposes of ERISA, is established or maintained by an employer;

c. A governmental or church plan defined in Section 414 of the Internal Revenue Code or a deferred compensation plan of a state or local government or a tax exempt organization under Section 457 of the Internal Revenue Code; or

d. A nonqualified deferred compensation arrangement established or maintained by an employer or plan sponsor.

Notwithstanding this subrule 15.62(2), these rules shall apply to annuities used to fund a plan or arrangement that is funded solely by contributions an employee elects to make whether on a pretax or after-tax basis, and where the insurance company has been notified that plan participants may choose from among two or more fixed annuity providers and there is a direct solicitation of an individual employee by a producer for the purchase of an annuity contract. As used in this subrule, direct solicitation shall not include any meeting held by a producer solely for the purpose of educating or enrolling employees in the plan or arrangement;

15.62(3) Structured settlement annuities;

15.62(4) Charitable gift annuities as defined in Iowa Code chapter 508F;

15.62(5) Nonregistered variable annuities issued exclusively to an accredited investor or qualified purchaser as those terms are defined by the Securities Act of 1933 (15 U.S.C. Section 77a et seq.), the Investment Company Act of 1940 (15 U.S.C. Section 80a-1 et seq.), or the regulations promulgated under either of those acts, and offered for sale and sold in a transaction that is exempt from registration under the Securities Act of 1933 (15 U.S.C. Section 77a et seq.); and

15.62(6) Transactions involving variable annuities and other registered products in compliance with Securities and Exchange Commission (SEC) rules and Financial Industry Regulatory Authority (FINRA) rules relating to disclosures and illustrations, provided that compliance with rule 191—15.64(507B) shall be required after January 1, 2015, unless, or until such time as, the SEC has adopted a summary prospectus rule or FINRA has approved for use a simplified disclosure form applicable to variable annuities or other registered products.

a. Notwithstanding this subrule 15.62(6), the delivery of the Buyer's Guide is required in sales of variable annuities and, when appropriate, in sales of other registered products.

b. Nothing in this subrule 15.62(6) shall limit the commissioner's ability to enforce the provisions of these rules or to require additional disclosure.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.63(507B) Definitions. For purposes of these rules:

"Buyer's Guide" means the National Association of Insurance Commissioners' approved Annuity Buyer's Guide.

"Contract owner" means the owner named in the annuity contract or the certificate holder in the case of a group annuity contract.

"Determinable elements" means elements that are derived from processes or methods that are guaranteed at issue and not subject to company discretion, but where the values or amounts cannot be determined until some point after the contract is issued. These elements include the premiums, credited

interest rates (including any bonus), benefits, values, non-interest-based credits, charges, or elements of formulas used to determine any of these elements. These elements may be described as guaranteed but not determined at issue. An element is considered determinable if it was calculated from underlying determinable elements only, or from both determinable and guaranteed elements.

“*Funding agreement*” means an agreement for an insurer to accept and accumulate funds and to make one or more payments at future dates in amounts that are not based on mortality or morbidity contingencies.

“*Generic name*” means a short title descriptive of the annuity contract for which application is made or an illustration is prepared, such as “single premium deferred annuity.”

“*Guaranteed elements*” means the premiums, credited interest rates (including any bonus), benefits, values, non-interest-based credits, charges, or elements of formulas used to determine any of these elements, that are guaranteed and determined at issue. An element is considered guaranteed if all of the underlying elements that go into its calculation are guaranteed.

“*Illustration*” means a personalized presentation or depiction that is prepared for and provided to an individual consumer and that includes nonguaranteed elements of an annuity contract over a period of years.

“*Market value adjustment*” or “*MVA*” is a positive or negative adjustment that may be applied to the account value or cash value of the annuity upon withdrawal, surrender, contract annuitization or death benefit payment based either on the movement of an external index or on the company’s current guaranteed interest rate being offered on new premiums or new rates for renewal periods, if that withdrawal, surrender, contract annuitization or death benefit payment occurs at a time other than on a specified guaranteed benefit date.

“*Nonguaranteed elements*” means the premiums, credited interest rates (including any bonus), benefits, values, non-interest-based credits, charges or elements of formulas used to determine any of these elements, that are subject to company discretion and are not guaranteed at issue. An element is considered nonguaranteed if any of the underlying nonguaranteed elements are used in its calculation.

“*Structured settlement annuity*” means a “qualified funding asset” as defined in Section 130(d) of the Internal Revenue Code or an annuity that would be a qualified funding asset under Section 130(d) but for the fact that it is not owned by an assignee under a qualified assignment.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.64(507B) Standards for the disclosure document and Buyer’s Guide.

15.64(1) Delivery methods. The documents required under this rule may be delivered as follows:

a. When an application for an annuity contract is taken in a face-to-face meeting, the applicant shall be given at or before the time of application both the disclosure document described in rule 191—15.65(507B) and the Buyer’s Guide, if any.

b. When an application for an annuity contract is taken by means other than a face-to-face meeting, the applicant shall be sent both the disclosure document and the Buyer’s Guide no later than five business days after the completed application is received by the insurer.

c. When an application is received as a result of direct solicitation through the mail:

(1) Providing a Buyer’s Guide in a mailing inviting prospective applicants to apply for an annuity contract shall be deemed to satisfy the requirement that the Buyer’s Guide be provided no later than five business days after receipt of the application.

(2) Providing a disclosure document in a mailing inviting a prospective applicant to apply for an annuity contract shall be deemed to satisfy the requirement that the disclosure document be provided no later than five business days after receipt of the application.

d. When an application is received via the Internet:

(1) Taking reasonable steps to make the Buyer’s Guide available for viewing and printing on the insurer’s Web site shall be deemed to satisfy the requirement that the Buyer’s Guide be provided no later than five business days after receipt of the application.

(2) Taking reasonable steps to make the disclosure document available for viewing and printing on the insurer's Web site shall be deemed to satisfy the requirement that the disclosure document be provided no later than five business days after receipt of the application.

15.64(2) *Free Buyer's Guide.* A solicitation for an annuity contract provided in other than a face-to-face meeting shall include a statement that the proposed applicant may contact the Iowa insurance division for a free Buyer's Guide. In lieu of the foregoing statement, an insurer may include a statement that the prospective applicant may contact the insurer for a free Buyer's Guide.

15.64(3) *Free-look period.* When the Buyer's Guide and disclosure document are not provided at or before the time of application, a free-look period of no less than 15 days shall be provided for the applicant to return the annuity contract without penalty. This free look shall run concurrently with any other free look provided under state law or rule.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.65(507B) Content of disclosure documents.

15.65(1) At a minimum, the following information shall be included in the disclosure document required to be provided under these rules:

a. The generic name of the contract, the company product name, if different, and form number and the fact that it is an annuity;

b. The insurer's legal name, physical address, Web site address and telephone number;

c. A description of the contract and its benefits, emphasizing its long-term nature, including examples where appropriate, including but not limited to:

(1) The guaranteed and nonguaranteed elements of the contract, and their limitations, if any, including for fixed indexed annuities, the elements used to determine the index-based interest, such as the participation rates, caps or spread, and an explanation of how they operate;

(2) An explanation of the initial crediting rate, or for fixed indexed annuities, an explanation of how the index-based interest is determined, specifying any bonus or introductory portion, the duration of the rate and the fact that rates may change from time to time and are not guaranteed;

(3) Periodic income options both on a guaranteed and nonguaranteed basis;

(4) Any value reductions caused by withdrawals from or surrender of the contract;

(5) How values in the contract can be accessed;

(6) The death benefit, if available, and how it will be calculated;

(7) A summary of the federal tax status of the contract and any penalties applicable on withdrawal of values from the contract; and

(8) Impact of any rider including, but not limited to, a guaranteed living benefit or a long-term care rider;

d. Specific dollar amount or percentage charges and fees, listed with an explanation of how they apply; and

e. Information about the current guaranteed rate or indexed crediting rate formula, if applicable, for new contracts that contains a clear notice that the rate is subject to change.

15.65(2) Insurers shall define terms used in the disclosure statement in language that facilitates understanding by a typical individual within the segment of the public to which the disclosure statement is directed.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.66(507B) Standards for annuity illustrations.

15.66(1) An insurer or producer may elect to provide a consumer an illustration at any time, provided that the illustration is in compliance with this rule and:

a. Is clearly labeled as an illustration;

b. Includes a statement referring consumers to the disclosure document and Buyer's Guide provided to them at time of purchase for additional information about their annuity; and

c. Is prepared by the insurer or third party using software that is authorized by the insurer prior to its use, provided that the insurer maintains a system of control over the use of illustrations.

15.66(2) An illustration furnished an applicant for a group annuity contract or contracts issued to a single applicant on multiple lives may be either an individual or composite illustration representative of the coverage on the lives of members of the group or the multiple lives covered.

15.66(3) The illustration shall not be provided unless accompanied by the disclosure document referenced in rules 191—15.64(507B) and 191—15.65(507B).

15.66(4) When an illustration is used, the illustration shall not:

- a. Describe nonguaranteed elements in a manner that is misleading or has the capacity or tendency to mislead;
- b. State or imply that the payment or amount of nonguaranteed elements is guaranteed; or
- c. Be incomplete.

15.66(5) Costs and fees of any type shall be individually noted and explained in the illustration.

15.66(6) An illustration shall conform to the following requirements:

- a. The illustration shall be labeled with the date on which it was prepared;
- b. Each page, including any explanatory notes or pages, shall be numbered and show its relationship to the total number of pages in the disclosure document (e.g., the fourth page of a seven-page disclosure document shall be labeled “page 4 of 7 pages”);
- c. The assumed dates of premium receipt and benefit payout within a contract year shall be clearly identified;
- d. If the age of the proposed insured is shown as a component of the tabular detail, the age shown shall be issue age plus the numbers of years the contract is assumed to have been in force;
- e. The assumed premium on which the illustrated benefits and values are based shall be clearly identified, including rider premium for any benefits being illustrated;
- f. Any charges for riders or other contract features assessed against the account value or the crediting rate shall be recognized in the illustrated values and shall be accompanied by a statement indicating the nature of the rider benefits or the contract features and indicating whether or not they are included in the illustration;
- g. Guaranteed death benefits and values available upon surrender, if any, for the illustrated contract premium shall be shown and clearly labeled as guaranteed;
- h. Except as provided by paragraph 15.66(6)“v,” nonguaranteed elements underlying the nonguaranteed illustrated values shall be no more favorable than current nonguaranteed elements and shall not include any assumed future improvement of such elements. Additionally, nonguaranteed elements used in calculating nonguaranteed illustrated values at any future duration shall reflect any planned changes, including any planned changes that may occur after expiration of an initial guaranteed or bonus period;
- i. In determining the nonguaranteed illustrated values for a fixed indexed annuity, the index-based interest rate and account value shall be calculated for three different scenarios: one to reflect historical performance of the index for the most recent 10 calendar years; one to reflect the historical performance of the index for the continuous period of 10 calendar years out of the last 20 calendar years that would result in the least index value growth (the “low scenario”); one to reflect the historical performance of the index for the continuous period of 10 calendar years out of the last 20 calendar years that would result in the most index value growth (the “high scenario”). The following requirements apply:
 - (1) The most recent 10 calendar years and the last 20 calendar years are defined to end on the prior December 31, except for illustrations prepared during the first three months of the year, for which the end date of the calendar year period may be the December 31 prior to the last full calendar year;
 - (2) If any index utilized in determination of an account value has not been in existence for at least 10 calendar years, indexed returns for that index shall not be illustrated. If the fixed indexed annuity provides an option to allocate account value to more than one indexed or fixed declared rate account, and one or more of those indexes has not been in existence for at least 10 calendar years, the allocation to such indexed account shall be assumed to be zero;
 - (3) If any index utilized in determination of an account value has been in existence for at least 10 calendar years but less than 20 calendar years, the 10-calendar-year periods that define the low and high scenarios shall be chosen from the exact number of years the index has been in existence;

(4) The nonguaranteed elements, such as caps, spreads, participation rates or other interest crediting adjustments, used in calculating the nonguaranteed index-based interest rate shall be no more favorable than the corresponding current elements;

(5) If a fixed indexed annuity provides an option to allocate the account value to more than one indexed or fixed declared rate account:

1. The allocation used in the illustration shall be the same for all three scenarios; and

2. The 10-calendar-year periods resulting in the least and greatest index growth periods shall be determined independently for each indexed account option;

(6) The geometric mean annual effective rate of the account value growth over the 10-calendar-year period shall be shown for each scenario;

(7) If the most recent 10-calendar-year historical period experience of the index is shorter than the number of years needed to fulfill the requirement of subrule 15.66(8), the most recent 10-calendar-year historical period experience of the index shall be used for each subsequent 10-calendar-year period beyond the initial period for the purpose of calculating the account value for the remaining years of the illustration;

(8) The low and high scenarios:

1. Need not show surrender values (if different than account values);

2. Shall not extend beyond 10 calendar years (and therefore are not subject to the requirements of subrule 15.66(8) beyond subparagraph 15.66(8)“a”(1)); and

3. May be shown on a separate page. A graphical presentation shall also be included comparing the movement of the account value over the 10-calendar-year period for the low scenario, the high scenario and the most recent 10-calendar-year scenario; and

(9) The low and high scenarios should reflect the irregular nature of the index performance and should trigger every type of adjustment to the index-based interest rate under the contract. The effect of the adjustments should be clear; for example, additional columns showing how the adjustment applied may be included. If an adjustment to the index-based interest rate is not triggered in the illustration (because no historical values of the index in the required illustration range would have triggered it), the illustration shall so state;

j. The guaranteed elements, if any, shall be shown before corresponding nonguaranteed elements and shall be specifically referred to on any page of an illustration that shows or describes only the nonguaranteed elements (e.g., “see page 1 for guaranteed elements”);

k. The account or accumulation value of a contract, if shown, shall be identified by the name this value is given in the contract being illustrated and shown in close proximity to the corresponding value available upon surrender;

l. The value available upon surrender shall be identified by the name this value is given in the contract being illustrated and shall be the amount available to the contract owner in a lump sum after deduction of surrender charges, bonus forfeitures, contract loans, contract loan interest and application of any market value adjustment, as applicable;

m. Illustrations may show contract benefits and values in graphic or chart form in addition to the tabular form;

n. Any illustration of nonguaranteed elements shall be accompanied by a statement indicating that:

(1) The benefits and values are not guaranteed;

(2) The assumptions on which they are based are subject to change by the insurer; and

(3) Actual results may be higher or lower;

o. Illustrations based on nonguaranteed credited interest and nonguaranteed annuity income rates shall contain equally prominent comparisons to guaranteed credited interest and guaranteed annuity income rates, including any guaranteed and nonguaranteed participation rates, caps or spreads for fixed indexed annuities;

p. The annuity income rate illustrated shall not be greater than the current annuity income rate unless the contract guarantees are in fact more favorable;

q. Illustrations shall be concise and easy to read;

r. Key terms shall be defined and then used consistently throughout the illustration;

- s. Illustrations shall not depict values beyond the maximum annuitization age or date;
 - t. Annuitization benefits shall be based on contract values that reflect surrender charges or any other adjustments, if applicable;
 - u. Illustrations shall show both annuity income rates per \$1,000 and the dollar amounts of the periodic income payable; and
 - v. For participating immediate and deferred income annuities:
 - (1) Illustrations shall not assume any future improvement in the applicable dividend scale (or scales, if more than one dividend scale applies, such as for a flexible premium annuity);
 - (2) Illustrations shall reflect the equitable apportionment of dividends, whether performance meets, exceeds or falls short of expectations;
 - (3) If the dividend scale is based on a portfolio rate method, the portfolio rate underlying the illustrated dividend scale shall not be assumed to increase;
 - (4) If the dividend scale is based on an investment cohort method, the illustrated dividend scale shall assume that reinvestment rates grade to long-term interest rates, subject to the following conditions:
 1. Any assumptions as to future investment performance in the dividend formula shall be consistent with assumptions that are reflected in the marketplace within the normal range of analyst forecasts and investor behavior. These assumptions shall not be changed arbitrarily, notwithstanding changes in markets or economic conditions, and shall be consistent with assumptions that the insurer uses with respect to other lines of business.
 2. The illustrated dividend scale shall assume that reinvestment rates grade to long-term interest rates, based on the rates of U.S. Treasury bonds (U.S. Treasury rates). For the purposes of this grading, the assumed long-term rates shall not exceed the rates calculated using the formula in numbered paragraph 15.66(6)“v”(4)“3” based on the time to maturity or reinvestment (the “tenor”) of the investments supporting the cohort of policies.
 3. Maximum long-term interest rates shall be calculated for tenors of 3 months or less, 5 years, 10 years, and 20 years or more, using U.S. Treasury rates. For each tenor, the maximum long-term interest rate shall vary over time, based on historical interest rates as they emerge. The formula for the maximum long-term interest rate is the average of the median U.S. Treasury rate during the last 600 months and the average U.S. Treasury rate during the last 120 months, rounded to the nearest quarter of one percent (0.25%).
 4. The maximum long-term interest rate for a tenor shall be recalculated once per year, in January, using historical interest rates as of December 31 of the calendar year two years prior to the calendar year of the calculation date. The historical interest rate for each month is the interest rate reported for the last business day of the month.
 5. Grading to the maximum long-term interest rates shall take place during:
 - No less than 20 years from the issue date if U.S. Treasury rates as of the illustration date are below the long-term interest rates; or
 - No more than 20 years from the issue date if the U.S. Treasury rates as of the illustration date are above the long-term interest rates.
 6. When the ten-year U.S. Treasury rate is less than the ten-year maximum long-term interest rate, an additional illustrated dividend scale shall be presented. This additional illustrated dividend scale shall satisfy the following conditions:
 - Assume that reinvestment U.S. Treasury rates do not exceed the initial investment U.S. Treasury rates, and
 - Illustrate dividends of no less than half of the dividends illustrated under the current dividend scales.
- If the conditions under the two prior bulleted paragraphs are in conflict (i.e., if half of the current dividends are greater than would be permitted by the condition under the first bulleted paragraph above), then the reinvestment U.S. Treasury rates shall equal the initial investment U.S. Treasury rates.
7. The illustration shall include a disclosure that is substantially similar to the following:

The illustrated current dividend scale is based on interest rates that are assumed to gradually [increase/decrease] from current interest rates to

long-term interest rates during a period of [20] years. As required by state regulations, the long-term assumed interest rates cannot and do not exceed the rates listed in column (c) of the table below.

[Insert table from paragraph 15.66(6) “v”(4)“9”]

8. If the illustration contains an additional dividend scale pursuant to numbered paragraph 15.66(6) “v”(4)“6,” then the illustration also shall include a disclosure that is substantially similar to the following:

The additional illustrated dividend scale is based on interest rates that are assumed not to increase and that do not exceed the interest rates in column (b) of the table below.

[Insert table from paragraph 15.66(6) “v”(4)“9”]

9. The following table shall be used in the disclosures as indicated in numbered paragraphs 15.66(6) “v”(4)“7” and “8”:

<u>(a)</u>	<u>(b)</u>	<u>(c)</u>
	<u>U.S. Treasury Rate as of 12/31/2016</u>	<u>Long-Term U.S. Treasury Rate</u>
3 Months or Less	0.51%	3.00%
5 Years	1.93%	4.50%
10 Years	2.45%	5.00%
20 Years or More	3.06%	5.50%

15.66(7) An annuity illustration shall include a narrative summary that includes the following unless provided at the same time in a disclosure document:

a. A brief description of any contract features, riders or options, whether guaranteed or nonguaranteed, shown in the basic illustration and the impact they may have on the benefits and values of the contract.

b. A brief description of any other optional benefits or features that are selected, but not shown in the illustration and the impact they have on the benefits and values of the contract.

c. Identification and a brief definition of column headings and key terms used in the illustration.

d. A statement containing in substance the following:

(1) For other than fixed indexed annuities:

This illustration assumes the annuity’s current nonguaranteed elements will not change. It is likely that they **will** change and actual values will be higher or lower than those in this illustration but will not be less than the minimum guarantees.

The values in this illustration are **not** guarantees or even estimates of the amounts you can expect from your annuity. Please review the entire Disclosure Document and Buyer’s Guide provided with your Annuity Contract for more detailed information.

(2) For fixed indexed annuities:

This illustration assumes the index will repeat historical performance and that the annuity’s current nonguaranteed elements, such as caps, spreads, participation rates or other interest crediting adjustments, will not change. It is likely that the index **will not** repeat historical performance, the nonguaranteed elements **will** change, and actual values will be higher or lower than those in this illustration but will not be less than the minimum guarantees.

The values in this illustration are **not** guarantees or even estimates of the amounts you can expect from your annuity. Please review the entire Disclosure Document and Buyer’s Guide provided with your Annuity Contract for more detailed information.

e. Additional explanations as follows:

(1) Minimum guarantees shall be clearly explained;

(2) The effect on contract values of contract surrender prior to maturity shall be explained;

(3) Any conditions on the payment of bonuses shall be explained;

(4) For annuities sold as an IRA or as a qualified plan or in another arrangement subject to the required minimum distribution (RMD) requirements of the Internal Revenue Code, the effect of RMDs on the contract values shall be explained;

(5) For annuities with recurring surrender charge schedules, a clear and concise explanation of what circumstances will cause the surrender charge to recur shall be included; and

(6) A brief description of the types of annuity income options available shall be explained, including:

1. The earliest or only maturity date for annuitization (as the term is defined in the contract);
2. For contracts with an optional maturity date, the periodic income amount for at least one of the annuity income options available based on the guaranteed rates in the contract, at the later of age 70 or 10 years after issue, but in no case later than the maximum annuitization age or date in the contract;
3. For contracts with a fixed maturity date, the periodic income amount for at least one of the annuity income options available, based on the guaranteed rates in the contract at the fixed maturity date; and
4. The periodic income amount based on the currently available periodic income rates for the annuity income option in numbered paragraph 15.66(7) "e"(6)"2" or "3," if desired.

15.66(8) Following the narrative summary, an illustration shall include a numeric summary which shall include, at minimum, numeric values at the following durations:

- a. Either:
 - (1) The first 10 contract years; or
 - (2) The surrender charge period if longer than 10 years, including any renewal surrender charge period;
- b. Every tenth contract year up to the later of 30 years or age 70; and
- c. Either:
 - (1) The required annuitization age; or
 - (2) The required annuitization date.

15.66(9) If the annuity contains a market value adjustment, hereafter MVA, all of the following provisions apply to the illustration (Appendix V provides an illustration of an annuity containing an MVA that addresses paragraphs 15.66(9) "a" through "f" below):

- a. The MVA shall be referred to as such throughout the illustration.
- b. The narrative shall include an explanation, in simple terms, of the potential effect of the MVA on the value available upon surrender.
- c. The narrative shall include an explanation, in simple terms, of the potential effect of the MVA on the death benefit.
- d. A statement, containing in substance the following, shall be included:

When you make a withdrawal, the amount you receive may be increased or decreased by a Market Value Adjustment (MVA). If interest rates on which the MVA is based go up after you buy your annuity, the MVA likely will decrease the amount you receive. If interest rates go down, the MVA will likely increase the amount you receive.
- e. Illustrations shall describe both the upside and the downside aspects of the contract features relating to the market value adjustment.
- f. The illustrative effect of the MVA shall be shown under at least one positive and one negative scenario. This demonstration shall appear on a separate page and be clearly labeled that it is information demonstrating the potential impact of an MVA.
- g. Actual MVA floors and ceilings as listed in the contract shall be illustrated.
- h. If the MVA has significant characteristics not addressed by paragraphs 15.66(9) "a" through "f," the effect of such characteristics shall be shown in the illustration.

15.66(10) A narrative summary for a fixed indexed annuity illustration also shall include the following unless provided at the same time in a disclosure document:

- a. An explanation, in simple terms, of the elements used to determine the index-based interest, including, but not limited to, the following elements:

- (1) The index(es) which will be used to determine the index-based interest;
- (2) The indexing method – such as point-to-point, daily averaging, monthly averaging;
- (3) The index term – the period over which indexed-based interest is calculated;
- (4) The participation rate, if applicable;
- (5) The cap, if applicable; and
- (6) The spread, if applicable;

b. The narrative shall include an explanation, in simple terms, of how index-based interest is credited in the indexed annuity;

c. The narrative shall include a brief description of the frequency with which the company can reset the elements used to determine the indexed-based credits, including the participation rate, the cap, and the spread, if applicable; and

d. If the product allows the contract holder to make allocations to declared-rate segment, then the narrative shall include a brief description of:

(1) Any options to make allocations to a declared-rate segment, both for new premiums and for transfers from the indexed-based segments; and

(2) Differences in guarantees applicable to the declared-rate segment and the indexed-based segments.

15.66(11) A numeric summary for a fixed indexed annuity illustration shall include, at a minimum, the following elements:

a. The assumed growth rate of the index in accordance with paragraph 15.66(6) “*i*”;

b. The assumed values for the participation rate, cap and spread, if applicable; and

c. The assumed allocation between indexed-based segments and declared-rate segment, if applicable, in accordance with paragraph 15.66(6) “*i*.”

15.66(12) If the contract is issued other than as applied for, a revised illustration conforming to the contract as issued shall be sent with the contract, except that nonsubstantive changes including, but not limited to, changes in the amount of expected initial or additional premiums and any changes in amounts of exchanges pursuant to Section 1035 of the Internal Revenue Code, rollovers or transfers, which do not alter the key benefits and features of the annuity as applied for will not require a revised illustration unless requested by the applicant.

[ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 4432C, IAB 5/8/19, effective 6/12/19]

191—15.67(507B) Report to contract owners. For annuities in the payout period that include nonguaranteed elements and for deferred annuities in the accumulation period, the insurer shall provide each contract owner with a report, at least annually, on the status of the contract that contains at least the following information:

15.67(1) The beginning and ending date of the current report period;

15.67(2) The accumulation and cash surrender value, if any, at the end of the previous report period and at the end of the current report period;

15.67(3) The total amounts, if any, that have been credited, charged to the contract value or paid during the current report period; and

15.67(4) The amount of outstanding loans, if any, as of the end of the current report period.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.68(507B) Penalties. In addition to any other penalties provided by the laws of this state, an insurer or producer that violates a requirement of these rules shall be guilty of a violation of Iowa Code chapter 507B.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.69(507B) Severability. If any provision of these rules or their application to any person or circumstance is for any reason held to be invalid by any court of law, the remainder of the rule and its application to other persons or circumstances shall not be affected.

[ARC 0035C, IAB 3/7/12, effective 4/11/12]

191—15.70 and 15.71 Reserved.

DIVISION V
SUITABILITY IN ANNUITY TRANSACTIONS

191—15.72(507B) Purpose. The purpose of these rules is to require producers, as defined in rule 191—15.74(507B), to act in the best interest of the consumer when making a recommendation of an annuity and to require insurers to establish and maintain a system to supervise recommendations so that the insurance needs and financial objectives of consumers at the times of the transactions are effectively addressed. Nothing herein shall be construed to create or imply a private cause of action for a violation of these rules or to subject a producer to civil liability under the best interest standard of care outlined in rule 191—15.75(507B) or under standards governing the conduct of a fiduciary or a fiduciary relationship.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.73(507B) Applicability and scope.

15.73(1) These rules shall apply to any sale or recommendation of an annuity on or after January 1, 2021.

15.73(2) Unless otherwise specifically included, these rules do not apply to transactions involving:

a. Direct-response solicitations where there is no recommendation based on information collected from the consumer pursuant to these rules;

b. Contracts used to fund the following:

(1) An employee pension or welfare benefit plan that is covered by the Employee Retirement and Income Security Act (ERISA);

(2) A plan described by Section 401(a), 401(k), 403(b), 408(k) or 408(p) of the Internal Revenue Code (IRC) if established or maintained by an employer;

(3) A government or church plan defined in Section 414 of the IRC, a government or church welfare benefit plan, or a deferred compensation plan of a state or local government or tax-exempt organization under Section 457 of the IRC; or

(4) A nonqualified deferred compensation arrangement established or maintained by an employer or plan sponsor;

c. Settlements or assumptions of liabilities associated with personal injury litigation or any dispute or claim resolution process; or

d. Formal prepaid funeral contracts.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.74(507B) Definitions. For purposes of this division:

“*Annuity*” means an annuity that is an insurance product under state law, individually solicited, whether the product is classified as an individual or group annuity.

“*Cash compensation*” means any discount, concession, fee, service fee, commission, sales charge, loan, override, or cash benefit received by a producer in connection with the recommendation or sale of an annuity from an insurer, intermediary, or directly from the consumer.

“*Consumer profile information*” means information that is reasonably appropriate to determine whether a recommendation addresses the consumer’s financial situation, insurance needs and financial objectives, including, at a minimum, the following:

1. Age;
2. Annual income;
3. Financial situation and needs, including debts and other obligations;
4. Financial experience;
5. Insurance needs;
6. Financial objectives;
7. Intended use of the annuity;

8. Financial time horizon;
9. Existing assets or financial products, including investment, annuity and insurance holdings;
10. Liquidity needs;
11. Liquid net worth;
12. Risk tolerance, including, but not limited to, willingness to accept nonguaranteed elements in the annuity;
13. Financial resources used to fund the annuity; and
14. Tax status.

“*Continuing education credit*” or “*CE credit*” means one credit as defined in rule 191—11.2(505,522B).

“*Continuing education provider*” or “*CE provider*” means a CE provider as defined in rule 191—11.2(505,522B).

“*FINRA*” means the Financial Industry Regulatory Authority or a succeeding agency.

“*Insurer*” means a company required to be licensed under the laws of this state to provide insurance products, including annuities.

“*Intermediary*” means an entity contracted directly with an insurer or with another entity contracted with an insurer to facilitate the sale of the insurer’s annuities by producers.

“*Material conflict of interest*” means a financial interest of the producer in the sale of an annuity that a reasonable person would expect to influence the impartiality of a recommendation. “Material conflict of interest” does not include cash compensation or noncash compensation.

“*Noncash compensation*” means any form of compensation that is not cash compensation, including, but not limited to, health insurance, office rent, office support and retirement benefits.

“*Nonguaranteed elements*” means the premiums, credited interest rates (including any bonus), benefits, values, dividends, non-interest based credits, charges or elements of formulas used to determine any of these, that are subject to company discretion and are not guaranteed at issue. An element is considered nonguaranteed if any of the underlying nonguaranteed elements are used in its calculation.

“*Producer*” means a person or entity required to be licensed under the laws of this state to sell, solicit or negotiate insurance, including annuities. For purposes of these rules, “producer” includes an insurer where no producer is involved.

“*Recommendation*” means advice provided by a producer to an individual consumer that was intended to result or does result in a purchase, an exchange or a replacement of an annuity in accordance with that advice. Recommendation does not include general communication to the public, generalized customer services assistance or administrative support, general educational information and tools, prospectuses, or other product and sales material.

“*Replacement*” means a transaction in which a new annuity is to be purchased, and it is known or should be known to the proposing producer, or to the proposing insurer whether or not a producer is involved, that, by reason of the transaction, an existing annuity or other insurance policy has been or is to be any of the following:

1. Lapsed, forfeited, surrendered or partially surrendered, assigned to the replacing insurer or otherwise terminated;
2. Converted to reduced paid-up insurance, continued as extended term insurance, or otherwise reduced in value by the use of nonforfeiture benefits or other policy values;
3. Amended so as to effect either a reduction in benefits or in the term for which coverage would otherwise remain in force or for which benefits would be paid;
4. Reissued with any reduction in cash value; or
5. Used in a financed purchase.

“*SEC*” means the United States Securities and Exchange Commission.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.75(507B) Duties of insurers and producers.

15.75(1) Best interest obligations. A producer, when making a recommendation of an annuity, shall act in the best interest of the consumer under the circumstances known at the time the recommendation is made, without placing the producer's or the insurer's financial interest ahead of the consumer's interest. A producer has acted in the best interest of the consumer if the producer has satisfied the following obligations regarding care, disclosure, conflict of interest and documentation:

a. Care obligation.

(1) The producer, in making a recommendation shall exercise reasonable diligence, care and skill to:

1. Know the consumer's financial situation, insurance needs and financial objectives;
2. Understand the available recommendation options after making a reasonable inquiry into options available to the producer;
3. Have a reasonable basis to believe the recommended option effectively addresses the consumer's financial situation, insurance needs and financial objectives over the life of the product, as evaluated in light of the consumer profile information; and
4. Communicate the basis or bases of the recommendation.

(2) The requirements under subparagraph 15.75(1) "a"(1) include making reasonable efforts to obtain consumer profile information from the consumer prior to the recommendation of an annuity.

(3) The requirements under subparagraph 15.75(1) "a"(1) require a producer to consider the types of products the producer is authorized and licensed to recommend or sell that address the consumer's financial situation, insurance needs and financial objectives. This does not require analysis or consideration of any products outside the authority and license of the producer or other possible alternative products or strategies available in the market at the time of the recommendation. Producers shall be held to standards applicable to producers with similar authority and licensure.

(4) The requirements under this subrule do not create a fiduciary obligation or relationship and only create a regulatory obligation as established in these rules.

(5) The consumer profile information, characteristics of the insurer, and product costs, rates, benefits and features are those factors generally relevant in making a determination whether an annuity effectively addresses the consumer's financial situation, insurance needs and financial objectives, but the level of importance of each factor under the care obligation of this paragraph may vary depending on the facts and circumstances of a particular case. However, each factor may not be considered in isolation.

(6) The requirements under subparagraph 15.75(1) "a"(1) include having a reasonable basis to believe the consumer would benefit from certain features of the annuity, such as annuitization, death or living benefit or other insurance-related features.

(7) The requirements under subparagraph 15.75(1) "a"(1) apply to the particular annuity as a whole and the underlying subaccounts to which funds are allocated at the time of purchase or exchange of an annuity, and riders and similar product enhancements, if any.

(8) The requirements under subparagraph 15.75(1) "a"(1) do not mean the annuity with the lowest one-time or multiple occurrence compensation structure shall necessarily be recommended.

(9) The requirements under subparagraph 15.75(1) "a"(1) do not mean the producer has ongoing monitoring obligations under the care obligation under this paragraph, although such an obligation may be separately owed under the terms of a fiduciary, consulting, investment advising or financial planning agreement between the consumer and the producer.

(10) In the case of an exchange or replacement of an annuity, the producer shall consider the whole transaction, which includes taking into consideration whether:

1. The consumer will incur a surrender charge, be subject to the commencement of a new surrender period, lose existing benefits, such as death, living or other contractual benefits, or be subject to increased fees, investment advisory fees or charges for riders and similar product enhancements;
2. The replacing product would substantially benefit the consumer in comparison to the replaced product over the life of the product; and
3. The consumer has had another annuity exchange or replacement and, in particular, an exchange or replacement within the preceding 60 months.

(11) Nothing in this regulation should be construed to require a producer to obtain any license other than a producer license with the appropriate line of authority to sell, solicit or negotiate insurance in this state, including but not limited to any securities license, in order to fulfill the duties and obligations contained in this regulation; provided the producer does not give advice or provide services that are otherwise subject to securities laws or engage in any other activity requiring other professional licenses.

b. Disclosure obligation.

(1) Prior to the recommendation or sale of an annuity, the producer shall prominently disclose to the consumer on a form substantially similar to Appendix VI:

1. A description of the scope and terms of the relationship with the consumer and the role of the producer in the transaction;

2. An affirmative statement on whether the producer is licensed and authorized to sell the following products:

- Fixed annuities;
- Fixed indexed annuities;
- Variable annuities;
- Life insurance;
- Mutual funds;
- Stocks and bonds; and
- Certificates of deposit;

3. An affirmative statement describing the insurers the producer is authorized, contracted (or appointed), or otherwise able to sell insurance products for, using the following descriptions:

- One insurer;
- From two or more insurers; or
- From two or more insurers although primarily contracted with one insurer.

4. A description of the sources and types of cash compensation and noncash compensation to be received by the producer, including whether the producer is to be compensated for the sale of a recommended annuity by commission as part of premium or other remuneration received from the insurer, intermediary or other producer or by fee as a result of a contract for advice or consulting services; and

5. A notice of the consumer's right to request additional information regarding cash compensation described in subparagraph 15.75(1) "b"(2);

(2) Upon request of the consumer or the consumer's designated representative, the producer shall disclose:

1. A reasonable estimate of the amount of cash compensation to be received by the producer, which may be stated as a range of amounts or percentages; and

2. Whether the cash compensation is a one-time or multiple occurrence amount, and if a multiple occurrence amount, the frequency and amount of the occurrence, which may be stated as a range of amounts or percentages; and

(3) Prior to or at the time of the recommendation or sale of an annuity, the producer shall have a reasonable basis to believe the consumer has been informed of various features of the annuity, such as: the potential surrender period and surrender charge; potential tax penalty if the consumer sells, exchanges, surrenders or annuitizes the annuity; mortality and expense fees; investment advisory fees; any annual fees; potential charges for and features of riders or other options of the annuity; limitations on interest returns; potential changes in nonguaranteed elements of the annuity; insurance and investment components; and market risk.

c. Conflict of interest obligation. A producer shall identify and avoid or reasonably manage and disclose material conflicts of interest, including material conflicts of interest related to an ownership interest.

d. Documentation obligation. A producer shall at the time of recommendation or sale:

(1) Make a written record of any recommendation and the basis for the recommendation subject to this regulation;

(2) Obtain a consumer-signed statement on a form substantially similar to Appendix VII documenting:

1. A customer's refusal to provide the consumer profile information, if any; and
2. A customer's understanding of the ramifications of not providing his or her consumer profile information or providing insufficient consumer profile information; and

(3) Obtain a consumer-signed statement on a form substantially similar to Appendix VIII acknowledging the annuity transaction is not recommended if a customer decides to enter into an annuity transaction that is not based on the producer's recommendation.

e. Application of the best interest obligation. Any requirement applicable to a producer under this subrule shall apply to every producer who has exercised material control or influence in the making of a recommendation and has received direct compensation as a result of the recommendation or sale, regardless of whether the producer has had any direct contact with the consumer. Activities such as providing or delivering marketing or educational materials, product wholesaling or other back office product support, and general supervision of a producer do not, in and of themselves, constitute material control or influence.

15.75(2) Transactions not based on a recommendation.

a. Except as provided under paragraph 15.75(2) "b," a producer shall have no obligation to a consumer under paragraph 15.75(1) "a" related to any annuity transaction if:

- (1) No recommendation is made;
- (2) A recommendation was made and was later found to have been prepared based on inaccurate material information provided by the consumer;
- (3) A consumer refuses to provide relevant consumer profile information and the annuity transaction is not recommended; or
- (4) A consumer decides to enter into an annuity transaction that is not based on a recommendation of the producer.

b. An insurer's issuance of an annuity subject to paragraph 15.75(2) "a" shall be reasonable under all the circumstances actually known to the insurer at the time the annuity is issued.

15.75(3) Supervision system.

a. Except as permitted under subrule 15.75(2), an insurer may not issue an annuity recommended to a consumer unless there is a reasonable basis to believe the annuity would effectively address the particular consumer's financial situation, insurance needs and financial objectives based on the consumer's consumer profile information.

b. An insurer shall establish and maintain a supervision system that is reasonably designed to achieve the insurer's and its producers' compliance with rules 191—15.72(507B) through 191—15.78(507B) including, but not limited to, the following:

(1) The insurer shall establish and maintain reasonable procedures to inform its producers of the requirements of these rules and shall incorporate the requirements of these rules into relevant producer training manuals;

(2) The insurer shall establish and maintain standards for producer product training and shall establish and maintain reasonable procedures to require its producers to comply with the requirements of rule 191—15.76(507B);

(3) The insurer shall provide product-specific training and training materials which explain all material features of its annuity products to its producers;

(4) The insurer shall establish and maintain procedures for the review of each recommendation prior to issuance of an annuity that are designed to ensure there is a reasonable basis to determine that the recommended annuity would effectively address the particular consumer's financial situation, insurance needs and financial objectives. Such review procedures may apply a screening system for the purpose of identifying selected transactions for additional review and may be accomplished electronically or through other means including, but not limited to, physical review. Such an electronic or other system may be designed to require additional review only of those transactions identified for additional review by the selection criteria;

(5) The insurer shall establish and maintain reasonable procedures to detect recommendations that are not in compliance with subrules 15.75(1), 15.75(2), 15.75(4) and 15.75(5). These procedures may include, but are not limited to, confirmation of the consumer's consumer profile information, systematic customer surveys, producer and consumer interviews, confirmation letters, producer statements or attestations, and programs of internal monitoring. Nothing in this subparagraph prevents an insurer from complying with this subparagraph by applying sampling procedures or by confirming the consumer profile information or other required information under this rule after issuance or delivery of the annuity;

(6) The insurer shall establish and maintain reasonable procedures to assess, prior to or upon issuance or delivery of an annuity, whether a producer has provided to the consumer the information required to be provided under this rule;

(7) The insurer shall establish and maintain reasonable procedures to identify and address suspicious consumer refusals to provide consumer profile information;

(8) The insurer shall establish and maintain reasonable procedures to identify and eliminate any sales contests, sales quotas, bonuses, and noncash compensation that are based on the sales of specific annuities within a limited period of time. The requirements of this subparagraph are not intended to prohibit the receipt of health insurance, office rent, office support, retirement benefits or other employee benefits by employees as long as those benefits are not based upon the volume of sales of a specific annuity within a limited period of time; and

(9) The insurer shall annually provide a written report to senior management, including to the senior manager responsible for audit functions, which details a review, with appropriate testing, reasonably designed to determine the effectiveness of the supervision system, the exceptions found, and corrective action taken or recommended, if any.

c. Third-party supervisor.

(1) Nothing in this subrule restricts an insurer from contracting for performance of a function (including maintenance of procedures) required under this subrule. An insurer is responsible for taking appropriate corrective action and may be subject to sanctions and penalties pursuant to rule 191—15.77(507B) regardless of whether the insurer contracts for performance of a function and regardless of the insurer's compliance with subparagraph 15.75(3) "c"(2).

(2) An insurer's supervision system under this subrule shall include supervision of contractual performance under this subrule including, but not limited to, the following:

1. Monitoring and, as appropriate, conducting audits to assure that the contracted function is properly performed; and

2. Annually obtaining a certification from a senior manager who has responsibility for the contracted function that the manager has a reasonable basis to represent, and does represent, that the function is properly performed.

d. An insurer is not required to include in its system of supervision:

(1) A producer's recommendations to consumers of products other than the annuities offered by the insurer; or

(2) Consideration of or comparison to options available to the producer or compensation relating to those options other than annuities or other products offered by the insurer.

15.75(4) Prohibited practices. Neither a producer nor an insurer shall dissuade, or attempt to dissuade, a consumer from:

a. Truthfully responding to an insurer's request for confirmation of the consumer profile information;

b. Filing a complaint; or

c. Cooperating with the investigation of a complaint.

15.75(5) Safe harbor.

a. Recommendations and sales of annuities made in compliance with comparable standards shall satisfy the requirements under these rules. This subrule applies to all recommendations and sales of annuities made by financial professionals in compliance with business rules, controls and procedures that satisfy a comparable standard even if such standard would not otherwise apply to the product or

recommendation at issue. However, nothing in this subrule shall limit the insurance commissioner's ability to investigate and enforce the provisions of these rules.

b. Nothing in paragraph 15.75(5)“*a*” shall limit the insurer's obligation to comply with paragraph 15.75(3)“*a*,” although the insurer may base its analysis on information received from either the financial professional or the entity supervising the financial professional.

c. For paragraph 15.75(5)“*a*” to apply, an insurer shall:

(1) Monitor the relevant conduct of the financial professional seeking to rely on paragraph 15.75(5)“*a*” or the entity responsible for supervising the financial professional, such as the financial professional's broker-dealer or an investment adviser registered under federal securities laws using information collected in the normal course of an insurer's business; and

(2) Provide to the entity responsible for supervising the financial professional seeking to rely on paragraph 15.75(5)“*a*,” such as the financial professional's broker-dealer or investment adviser registered under federal securities laws, information and reports that are reasonably appropriate to assist such entity to maintain its supervision system.

d. For purposes of this subrule, “financial professional” means a producer that is regulated and acting as:

(1) A broker-dealer registered under federal securities laws or a registered representative of a broker-dealer;

(2) An investment adviser registered under federal securities laws or an investment adviser representative associated with the federal registered investment adviser; or

(3) A plan fiduciary under Section 3(21) of the Employee Retirement Income Security Act of 1974 (ERISA) or fiduciary under Section 4975(e)(3) of the Internal Revenue Code (IRC) or any amendments or successor statutes thereto.

e. For purposes of this subrule, “comparable standards” means:

(1) With respect to broker-dealers and registered representatives of broker-dealers, applicable SEC and FINRA rules pertaining to best interest obligations and supervision of annuity recommendations and sales, including, but not limited to, Regulation Best Interest and any amendments or successor regulations thereto;

(2) With respect to investment advisers registered under federal securities laws or investment adviser representatives, the fiduciary duties and all other requirements imposed on such investment advisers or investment adviser representatives by contract or under the Investment Advisers Act of 1940, including, but not limited to, the Form ADV and interpretations; and

(3) With respect to plan fiduciaries or fiduciaries, means the duties, obligations, prohibitions and all other requirements attendant to such status under ERISA or the IRC and any amendments or successor statutes thereto.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.76(507B) Producer training.

15.76(1) A producer shall not solicit the sale of an annuity product unless the producer has adequate knowledge of the product to recommend the annuity and the producer is in compliance with the insurer's standards for product training. A producer may rely on insurer-provided product-specific training standards and materials to comply with this subrule.

15.76(2) Training required.

a. One-time course.

(1) A producer who engages in the sale of annuity products shall complete a one-time four-credit training course approved by the commissioner and provided by an education provider approved by the commissioner.

(2) Producers may not engage in the sale of annuities until the annuity training course required under this rule has been completed.

b. The minimum length of the training required under this rule shall be sufficient to qualify for at least four CE credits, but may be longer.

- c.* The training required under this rule shall include information on the following topics:
- (1) The types of annuities and various classifications of annuities;
 - (2) Identification of the parties to an annuity;
 - (3) How fixed, variable, indexed, and other product-specific annuity contract provisions affect consumers;
 - (4) The application of income taxation of qualified and nonqualified annuities;
 - (5) The primary uses of annuities;
 - (6) Appropriate standard of conduct sales practices; and
 - (7) Replacement and disclosure requirements.
- d.* Providers of courses intended to comply with this rule shall cover all topics listed in the prescribed outline and shall not present any marketing information or provide training on sales techniques or provide specific information about a particular insurer's products. Additional topics may be offered in conjunction with and in addition to the required outline.
- e.* A provider of an annuity training course intended to comply with this rule shall register as a CE provider in this state and comply with the rules and guidelines applicable to producer continuing education courses as set forth in 191—Chapter 11.
- f.* A producer who has completed an annuity training course approved by the commissioner prior to January 1, 2021, shall, before July 1, 2021, complete either:
- (1) A new four-credit training course approved by the commissioner after January 1, 2021; or
 - (2) An additional one-time one-credit training course approved by the commissioner and provided by the commissioner-approved education provider on appropriate sales practices, replacement and disclosure requirements under this amended regulation.
- g.* Annuity training courses may be conducted and completed by classroom or self-study methods in accordance with 191—Chapter 11.
- h.* Providers of annuity training shall comply with the reporting requirements and shall issue certificates of completion in accordance with 191—Chapter 11.
- i.* Satisfaction of the training requirements of another state that are substantially similar to the provisions of this subrule shall be deemed to satisfy the training requirements of this subrule in this state.
- j.* The satisfaction of the components of the training requirements of any course or courses with components substantially similar to the provisions of this subrule shall be deemed to satisfy the training requirements of this subrule in this state.
- k.* An insurer shall verify that a producer has completed the annuity training course required under this subrule before allowing the producer to sell an annuity product for that insurer. An insurer may satisfy its responsibility under this subrule by obtaining certificates of completion of the training course or obtaining reports provided by Iowa insurance commissioner-sponsored database systems or vendors or from a reasonably reliable commercial database vendor that has a reporting arrangement with approved continuing education providers.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.77(507B) Compliance; mitigation; penalties; enforcement.

15.77(1) An insurer is responsible for compliance with this regulation. If a violation occurs, either because of the action or inaction of the insurer or its producer, the commissioner may order:

- a.* An insurer to take reasonably appropriate corrective action for any consumer harmed by a failure to comply with these rules by the insurer, an entity contracted to perform the insurer's supervisory duties, or by the producer;
- b.* A general agency, independent agency or the producer to take reasonably appropriate corrective action for any consumer harmed by the producer's violation of the rules of this division; and
- c.* Appropriate penalties and sanctions.

15.77(2) Any applicable penalty under Iowa Code chapter 507B for a violation of the rules in Division V of this chapter may be reduced or eliminated if corrective action for the consumer was taken promptly after a violation was discovered or the violation was not part of a pattern or practice.

15.77(3) The authority to enforce compliance with these rules is vested exclusively with the commissioner.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.78(507B) Record keeping.

15.78(1) Insurers, general agents, independent agencies, and producers shall maintain or be able to make available to the commissioner records of the information collected from the consumer, disclosures made to the consumer (including summaries of oral disclosures) and other information used in making the recommendations that were the basis for insurance transactions for ten years after the insurance transaction is completed by the insurer. An insurer is permitted, but shall not be required, to maintain documentation on behalf of a producer.

15.78(2) Records required to be maintained by this rule may be maintained in paper, photographic, microprocess, magnetic, mechanical or electronic media or by any process that accurately reproduces the actual document.

[ARC 8934B, IAB 7/14/10, effective 1/1/11; ARC 0035C, IAB 3/7/12, effective 4/11/12; ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

191—15.79 Reserved.

DIVISION VI INDEXED PRODUCTS TRAINING REQUIREMENT

191—15.80(507B,522B) Purpose. The purpose of the rules in this division is to require certain specific minimum training for insurance producers who wish to sell indexed annuities or indexed life insurance in Iowa. This additional training is necessary due to the complex nature of these indexed products and to ensure that insurance producers are able to determine whether an indexed product is suitable for a consumer and are able to adequately explain to a consumer how the indexed product works. The ultimate goal of these rules is to ensure that purchasers of indexed products understand basic features of the indexed products. The rules in this division apply to all indexed products sold on or after January 1, 2008.

191—15.81(507B,522B) Definitions. For the purpose of this division:

“*CE credit*” means one continuing education “credit” as defined in 191—Chapter 11.

“*CE provider*” means any individual or entity that is approved to offer continuing education courses in Iowa pursuant to 191—Chapter 11.

“*Indexed products*” means all fixed indexed life insurance and fixed indexed annuity products.

“*Insurer*” means an insurance company admitted to do business in Iowa which sells indexed products in Iowa.

“*Producer*” means a person required to obtain an insurance license under Iowa Code chapter 522B.

191—15.82(507B,522B) Special training required. A producer who wishes to sell indexed products in Iowa shall complete at least one four-credit indexed products training course, as described in this division, prior to providing any advice or making any sales presentation concerning an indexed product.

191—15.83(507B,522B) Conduct of training course.

15.83(1) The indexed products training shall include information on all topics listed in the most recent version of the indexed products training outline available at the division’s Web site, www.iid.iowa.gov.

15.83(2) CE providers of indexed products training shall cover all topics listed in the indexed products training outline and, within the time allotted for the required topics, shall not present any

marketing information or provide training on sales techniques or provide specific information about a particular insurer's products. Additional topics may be offered in conjunction with and in addition to the required outline.

15.83(3) The minimum length of the indexed products training must be sufficient to qualify for at least four CE credits, but may be longer.

15.83(4) To satisfy the requirements of subrules 15.83(1), 15.83(2) and 15.83(3), an indexed products training course shall be filed, approved and conducted according to the rules and guidelines applicable to insurance producer continuing education courses as set forth in 191—Chapter 11.

15.83(5) Indexed products training courses may be conducted and completed by classroom or self-study methods according to the rules in 191—Chapter 11.

15.83(6) CE providers of indexed products training shall comply with the reporting requirements as set forth in 191—Chapter 11.

15.83(7) CE providers of indexed products training shall issue certificates of completion according to the rules in 191—Chapter 11.

15.83(8) A producer may use the CE credits completed under the indexed products training requirement to meet the producer's continuing education requirement under 191—Chapter 11.

[ARC 2296C, IAB 12/9/15, effective 1/13/16]

191—15.84(507B,522B) Insurer duties.

15.84(1) Each insurer shall establish a system to verify which of its appointed insurance producers have completed one training course on indexed products as required in this division.

15.84(2) An insurer shall verify that a producer has completed the required indexed products training before allowing the producer to sell an indexed product for that insurer.

15.84(3) For insurance producers under contract with or employed by a broker-dealer, general agent or independent agency, an insurer may enter into a contract with the broker-dealer, general agent or independent agency to establish and maintain a system of verification as required by subrule 15.84(1) with respect to those insurance producers. In such circumstances, the insurer shall make reasonable inquiry to ensure that the broker-dealer, general agent or independent agency is performing the functions required under subrules 15.84(1) and 15.84(2).

191—15.85(507B,522B) Verification of training. Insurers, producers and third-party contractors may verify a producer's completion of the indexed products training by accessing the division's Web site at www.iid.iowa.gov.

[ARC 2296C, IAB 12/9/15, effective 1/13/16]

191—15.86(507B,522B) Penalties.

15.86(1) Insurers and third-party contractors that violate the rules of this division are subject to penalty under Iowa Code chapter 507B.

15.86(2) Producers who violate the rules of this division are subject to penalty under Iowa Code chapters 507B and 522B.

15.86(3) Continuing education providers that fail to follow the requirements of the rules of this division and the conduct requirements of 191—Chapter 11 are subject to penalty under 191—Chapter 11 and Iowa Code chapters 507B and 522B.

191—15.87(507B,522B) Compliance date.

15.87(1) A producer who provides advice or makes a sales presentation regarding an indexed product on or after January 1, 2008, shall have completed the indexed products training required by this division.

15.87(2) An Iowa-licensed insurer shall verify that, prior to the sale of any indexed products on or after January 1, 2008, any producer appointed by the insurer has completed the indexed products training required by this division.

APPENDIX I
LIFE INSURANCE COST AND
BENEFIT DISCLOSURE

Definitions.

“Annual premium” for a basic policy or rider, for which the company reserves the right to change the premium, shall be the maximum annual premium.

“Cash dividend” means dividends which can be applied toward payment of gross premiums which comply with the illustrated scale.

“Equivalent level annual dividend” is calculated by applying the following steps:

1. Accumulate the annual cash dividends at 5 percent interest compounded annually to the end of the tenth and twentieth policy years.

2. Divide each accumulation of paragraph “1” by an interest factor that converts it into one equivalent level annual amount that, if paid at the beginning of each year, would accrue to the values in paragraph “1” over the respective periods stipulated in paragraph “1.” If the period is 10 years, the factor is 13.207 and if the period is 20 years, the factor is 34.719.

3. Divide the results of paragraph “2” by the number of thousands of the equivalent level death benefit to arrive at the equivalent level annual dividend.

“Equivalent level death benefit” of a policy or term life insurance rider is an amount calculated as follows:

1. Accumulate the guaranteed amount payable upon death, regardless of the cause of death other than suicide, or other specifically enumerated exclusions, at the beginning of each policy year for 10 and 20 years at 5 percent interest compounded annually to the end of the tenth and twentieth policy years respectively.

2. Divide each accumulation of paragraph “1” by an interest factor that converts it into one equivalent level annual amount that, if paid at the beginning of each year, would accrue to the value in paragraph “1” over the respective periods stipulated in paragraph “1.” If the period is 10 years, the factor is 13.207 and if the period is 20 years, the factor is 34.719.

“Generic name” means a short title which is descriptive of the premium and benefit patterns of a policy or a rider.

“Life insurance net payment cost index.” The life insurance net payment cost index is calculated in the same manner as the comparable life insurance cost index except that the cash surrender value and any terminal dividend are set at zero.

“Life insurance surrender cost index.” The life insurance surrender cost index is calculated by applying the following steps:

1. Determine the guaranteed cash surrender value, if any, available at the end of the tenth and twentieth policy years.

2. For participating policies, add the terminal dividend payable upon surrender, if any, to the accumulation of the annual cash dividends at 5 percent interest compounded annually to the end of the period selected and add this sum to the amount determined in subparagraph “1.”

3. Divide the result of subparagraph “2” (subparagraph “1” for guaranteed-cost policies) by an interest factor that converts it into an equivalent level annual amount that, if paid at the beginning of each year, would accrue to the value in subparagraph “2” (subparagraph “1” for guaranteed-cost policies) over the respective periods stipulated in subparagraph “1.” If the period is 10 years, the factor is 13.207 and if the period is 20 years, the factor is 34.719.

4. Determine the equivalent level premium by accumulating each annual premium payable for the basic policy or rider at 5 percent interest compounded annually to the end of the period stipulated in subparagraph “1” and dividing the result by the respective factors stated in subparagraph “3” (this amount is the annual premium payable for a level premium plan).

5. Subtract the result of subparagraph “3” from subparagraph “4.”

6. Divide the result of subparagraph “5” by the number of thousands of the equivalent level death benefit to arrive at the life insurance surrender cost index.

“Policy summary,” for the purposes of these rules, shall mean a written statement describing the elements of the policy including but not limited to:

1. A prominently placed title as follows: STATEMENT OF POLICY COST AND BENEFIT INFORMATION.

2. The name and address of the insurance producer or, if no producer is involved, a statement of the procedure to be followed in order to receive responses to inquiries regarding the policy summary.

3. The full name and home office or administrative office address of the company in which the life insurance policy is to be or has been written.

4. The generic name of the basic policy and each rider.

5. The following amounts, where applicable, for the first five policy years and representative policy years thereafter sufficient to clearly illustrate the premium and benefit patterns including, but not necessarily limited to, the years for which life insurance cost indexes are displayed and at least one age from 60 through 65 or maturity, whichever is earlier:

(a) The annual premium for the basic policy.

(b) The annual premium for each optional rider.

(c) Guaranteed amount payable upon death, at the beginning of the policy year regardless of the cause of death other than suicide and other specifically enumerated exclusions, which is provided by the basic policy and each optional rider, with benefits provided under the basic policy and each rider shown separately.

(d) Total guaranteed cash surrender values at the end of the year with values shown separately for the basic policy and each rider.

(e) Cash dividends payable at the end of the year with values shown separately for the basic policy and each rider. (Dividends need not be displayed beyond the twentieth policy year.)

(f) Guaranteed endowment amounts payable under the policy which are not included under guaranteed cash surrender values above.

6. The effective policy loan annual percentage interest rate, if the policy contains this provision, specifying whether this rate is applied in advance or in arrears. If the policy loan interest rate is variable, the policy summary includes the maximum annual percentage rate.

7. Life insurance cost indexes for 10 and 20 years but in no case beyond the premium paying period. Separate indexes are displayed for the basic policy and for each optional term life insurance rider. Such indexes need not be included for optional riders which are limited to benefits such as accidental death benefits, disability waiver of premium, preliminary term life insurance coverage of less than 12 months and guaranteed insurability benefits nor for basic policies or optional riders covering more than one life.

8. The equivalent level annual dividend, in the case of participating policies and participating optional term life insurance riders, under the same circumstances and for the same durations at which life insurance cost indexes are displayed.

9. A policy summary which includes dividends shall also include a statement that dividends are based on the company’s illustrated scale and are not guaranteed and a statement in close proximity to the equivalent level annual dividend as follows: An explanation of the intended use of the equivalent level annual dividend is included in the life insurance buyer’s guide.

10. A statement in close proximity to the life insurance cost indexes as follows: An explanation of the intended use of these indexes is provided in the life insurance buyer’s guide.

11. The date on which the policy summary is prepared.

The policy summary must consist of a separate document. All information required to be disclosed must be set out in such a manner as not to minimize or render any portion thereof obscure. Any amounts which remain level for two or more years of the policy may be represented by a single number if it is clearly indicated what amounts are applicable for each policy year. Amounts in paragraph “5” of this definition shall be listed in total, not a per-thousand nor a per-unit basis. If more than one insured is covered under one policy or rider, guaranteed death benefits shall be displayed separately for each insured or for each class of insured if death benefits do not differ within the class. Zero amounts shall be displayed as zero and shall not be displayed as a blank space.

APPENDIX II
HIV ANTIBODY TEST
INFORMATION FORM FOR INSURANCE APPLICANT

AIDS

Acquired Immunodeficiency Syndrome (AIDS) is a life-threatening disorder of the immune system, caused by a virus, HIV. The virus is transmitted by sexual contact with an infected person, from an infected mother to her newborn infant, or by exposure to infected blood (as in needle sharing during IV drug use). Persons at high risk of contracting AIDS include males who have had sexual contact with another man, intravenous drug users, hemophiliacs, and persons who have had sexual contact with any of these persons. AIDS does not typically develop until a person has been infected with HIV for several years. A person may remain free of symptoms for years after becoming infected. Infected persons have a 25 percent to 50 percent chance of developing AIDS over the next ten years.

The HIV antibody test:

Before consenting to testing, please read the following important information:

1. Purpose. This test is being run to determine whether you may have been infected with HIV. If you are infected, you are probably not insurable. This test is not a test for AIDS; AIDS can only be diagnosed by medical evaluation.

2. Positive test results. If you test positive, you should seek medical follow-up with your personal physician. If your test is positive, you may be infected with HIV.

3. Accuracy. An HIV test will be considered positive only after confirmation by a laboratory procedure that the state health officer has determined to be highly accurate. Nonetheless, the HIV antibody test is not 100 percent accurate. Possible errors include:

a. False positives: This test gives a positive result, even though you are not infected. This happens rarely and is more common in persons who have not engaged in high-risk behavior. Retesting should be done to help confirm the validity of a positive test.

b. False negatives: The test gives a negative result, even though you are infected with HIV. This happens most commonly in recently infected persons; it takes at least 4 to 12 weeks for a positive test result to develop after a person is infected.

4. Side effects. A positive test result may cause you significant anxiety. A positive test may result in uninsurability for life, health, or disability insurance policies for which you may apply in the future. Although prohibited by law, discrimination in housing, employment, or public accommodations may result if your test results become known to others. A negative result may create a false sense of security.

5. Disclosure of results. A positive test result will be reported to you in one of the following ways. You may choose to have information about a positive test result communicated to you through your physician or through the alternative testing site. If you do not designate a physician or an alternative testing site to receive the information, the information about a positive test result will be reported to the Iowa Department of Public Health, and the Iowa Department of Public Health will contact you.

6. Confidentiality. Like all medical information, HIV test results are confidential. An insurer, insurance agent, or insurance-support organization is required to maintain the confidentiality of HIV test results. However, certain disclosures of your test results may occur, including those authorized by consent forms that you may have signed as part of your overall application. Your test results may be provided to the Medical Information Bureau, a national insurance data bank. Your insurance agent will provide you with additional written information about this subject at your request.

7. Prevention. Persons who have a history of high-risk behavior should change these behaviors to prevent getting or giving AIDS, regardless of whether they are tested. Specific important changes in behavior include safe sex practices (including condom use for sexual contact with someone other than a long-term monogamous partner) and not sharing needles.

8. Information. Further information about HIV testing and AIDS can be obtained by contacting the CDC national health information hotline, 1-800-CDC-INFO (1-800-232-4636); TTY 1-888-232-6348; www.cdc.gov/info.

APPENDIX III
COMPLAINT RECORD

Column A	Column B		Column C	Column D	Column E	Column F	Column G	Column H
Company Identification Number	Function Code	Reason Code	Line Type	Company Disposition after Complaint Received	Date Received	Date Closed	Insurance Division Complaint	State of Origin

(Producer's
Number)

Explanation

- A. Company Identification Number. As noted, this refers to the identification number of the complainant and shall also include the license number, name, or other means of identifying any licensee of the Insurance Division, such as a producer that may have been involved in the complaint.
- B. Function Code. Complaints are to be classified by function(s) of the company involved. Separate classifications are to be maintained for underwriting, marketing and sales, claims, policyholder service and miscellaneous.
- Reason Code. Complaints are also to be classified by the nature of the complaint. The following is the classification required for each function specified above.
- 1) Underwriting
 - a) Premium and rating
 - b) Refusal to insure
 - c) Cancellation/renewal
 - d) Delays
 - e) Unfair discrimination
 - f) Endorsement/rider
 - g) Group conversion
 - h) Medicare supplement violation
 - i) Miscellaneous (not covered by above)
 - 2) Marketing and Sales
 - a) General advertising
 - b) Misrepresentation
 - c) Producer handling
 - d) Replacement
 - e) Delays
 - f) Miscellaneous (not covered by above)
 - 3) Claims
 - a) Post claim underwriting
 - b) Delays
 - c) Unsatisfactory settlement/offer
 - d) Coordination of benefits
 - e) Cost containment
 - f) Denial of claim
 - g) Miscellaneous (not covered by above)
 - 4) Policyholder service
 - a) Premium notice/billing
 - b) Cash value
 - c) Delays/no response
 - d) Premium refund
 - e) Coverage question
 - f) Miscellaneous (not covered by above)
 - 5) Miscellaneous

- C. Line Type. Complaints are to be classified according to the line of insurance involved as follows:
- 1) Automobile
 - 2) Fire
 - 3) Homeowners-Farmowners
 - 4) Crop
 - 5) Life and Annuity
 - 6) Accident and Health
 - 7) Miscellaneous (not covered by above)
- D. Company Disposition After Receipt. The complaint record shall note the disposition of the complaint.
The following examples illustrate the type of information called for, but are not intended to be required language nor to exhaust the possibilities:
1. Policy issued/restored.
 2. Refund.
 3. Claim settled.
 4. Delay resolved.
 5. Question of fact.
 6. Contract provision/legal issue.
 7. No jurisdiction.
- E. Date Received. This refers to the date the complaint was received.
- F. Date Closed. This refers to the date on which the complaint was disposed of whether by one action or a series of actions as may be present in connection with some complaints.
- G. Insurance Department Complaint. Complaints are to be classified so as to indicate if the complaint was from an insurance department.
- H. State of Origin. The complaint record should note the state from which the complaint originated. Ordinarily this will be the state of residence of the complainant.

APPENDIX IV
DISCLOSURE FORM FOR SMALL FACE AMOUNT LIFE INSURANCE POLICIES

Important Information About Your Policy

The premiums you'll pay for your policy may be more than the amount of your coverage (the face amount). You can find both the face amount and the annual premium in your policy. Look for the page labeled [use the label the company uses for that information, such as "Statement of Policy Cost and Benefit Information"].

- Usually, you can figure out how many years it will take until the premiums paid will be greater than the face amount. For an estimate, divide the face amount by the annual premium. Several factors may affect how many years this might take for *your* policy. These include not paying premiums when due, taking out a policy loan, surrendering your policy for cash, policy riders, payment of dividends, if applicable, and changes in the face amount.
- Many factors will affect how much your life insurance costs. Some are your age and health, the face amount of the policy, and the cost of a policy rider. You may be able to pay less for your insurance if you answer health questions. You may also pay less if you pay your premiums less often.
- Ask your insurance agent or your insurance company if you have any questions about your premiums, your coverage, or anything else about your policy.

If You Change Your Mind . . .

- You can get a full refund of premiums you've paid if you return your policy and cancel your coverage. You *must* do this within the number of days stated on your policy's front page. To return the policy for a full refund, send it back to the agent or the company.
- If you stop paying premiums or cancel your policy *after* the time that a full refund is available, you have specific rights. Ask your insurance agent or your insurance company about your rights.

Contact Information

If you have questions about your insurance policy, ask your agent or your company. If your agent isn't available, contact your insurance company at [provide telephone number (including toll-free number if available), address and Web site (if available)].

APPENDIX V

Annuity Illustration Example

[The following illustration is an example only and does not reflect specific characteristics of any actual product for sale by any company]

ABC Life Insurance Company

Company Product Name

Flexible Premium Fixed Deferred Annuity with a Market Value Adjustment (MVA)

An Illustration Prepared for John Doe by John Agent on mm/dd/yyyy

(Contact us at Policyownerservice@ABCLife.com or 555-555-5555.)

Sex: Male	Initial Premium Payment: \$100,000.00
Age at Issue: 54	Planned Annual Premium Payments: None
Annuitant: John Doe	Tax Status: Nonqualified
Oldest Age at Which Annuity Payments Can Begin: 95	Withdrawals: None Illustrated

Initial Interest Guarantee Period	5 Years
Initial Guaranteed Interest Crediting Rates	
First Year (reflects first year only interest bonus credit of 0.75%):	4.15%
Remainder of Initial Interest Guarantee Period:	3.40%
Market Value Adjustment Period:	5 Years
Minimum Guaranteed Interest Rate After Initial Interest Guarantee Period*:	3%

*After the Initial Interest Guarantee Period, a new interest rate will be declared annually. This rate cannot be lower than the Minimum Guaranteed Interest Rate.

Annuity Income Options and Illustrated Monthly Income Values

This annuity is designed to pay an income that is guaranteed to last as long as the Annuitant lives. When annuity income payments are to begin, the income payment amounts will be determined by applying an annuity income rate to the annuity Account Value.

Annuity income options include the following:

- Periodic payments for Annuitant’s life
- Periodic payments for Annuitant’s life with payments guaranteed for a certain number of years
- Periodic payments for Annuitant’s life with payments continuing for the life of a survivor annuitant

Illustrated Annuity Income Option: Monthly payments for Annuitant’s life with payments guaranteed for 10-year period.

Assumed Age When Payments Start: 70

	Account Value	Monthly Annuity Income Rate/\$1,000 of Account Value*	Monthly Annuity Income
Based on Rates Guaranteed in the Contract	\$164,798	\$5.00	\$823.99
Based on Rates Currently Offered by the Company	\$171,976	\$6.50	\$1,117.84

*If, at the time of annuitization, the annuity income rates currently offered by the company are higher than the annuity income rates guaranteed in the contract, the current rates will apply.

ABC Life Insurance Company*Company Product Name*

Flexible Premium Fixed Deferred Annuity with a Market Value Adjustment (MVA)

An Illustration Prepared for John Doe by John Agent on mm/dd/yyyy

(Contact us at Policyownerservice@ABCLife.com or 555-555-5555.)

Contract Year/Age	Premium Payment	Values Based on Guaranteed Rates				Values Based on Assumption That Initial Guaranteed Rates Continue		
		Interest Crediting Rate	Account Value	Cash Surrender Value Before MVA	Minimum Cash Surrender Value After MVA	Interest Crediting Rate	Account Value	Cash Surrender Value Before and After MVA
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1 / 55	\$ 100,000	4.15%	\$ 104,150	\$ 95,818	\$ 92,000	4.15%	\$ 104,150	\$ 95,818
2 / 56	0	3.40%	107,691	100,153	93,000	3.40%	107,691	100,513
3 / 57	0	3.40%	111,353	104,671	95,614	3.40%	111,353	104,671
4 / 58	0	3.40%	115,139	109,382	98,482	3.40%	115,139	109,382
5 / 59	0	3.40%	119,053	114,291	114,291	3.40%	119,053	114,291
6 / 60	0	3.00%	122,625	118,946	118,946	3.40%	123,101	119,408
7 / 61	0	3.00%	126,304	123,778	123,778	3.40%	127,287	124,741
8 / 62	0	3.00%	130,093	130,093	130,093	3.40%	131,614	131,614
9 / 63	0	3.00%	133,996	133,996	133,996	3.40%	136,089	136,089
10 / 64	0	3.00%	138,015	138,015	138,015	3.40%	140,716	140,716
11 / 65	0	3.00%	142,156	142,156	142,156	3.40%	145,501	145,501
16 / 70	0	3.00%	164,798	164,798	164,798	3.40%	171,976	171,976
21 / 75	0	3.00%	191,046	191,046	191,046	3.40%	203,268	203,268
26 / 80	0	3.00%	221,474	221,474	221,474	3.40%	240,255	240,255
31 / 85	0	3.00%	256,749	256,749	256,749	3.40%	283,972	283,972
36 / 90	0	3.00%	297,643	297,643	297,643	3.40%	335,643	335,643
41 / 95	0	3.00%	345,050	345,050	345,050	3.40%	396,717	396,717

For column descriptions, turn to page 3

Column Descriptions

- (1) **Ages** shown are measured from the Annuitant's age at issue.
- (2) **Premium Payments** are assumed to be made at the beginning of the Contract Year shown.

Values Based on Guaranteed Rates

- (3) **Interest Crediting Rates** shown are annual rates; however, interest is credited daily. During the Initial Interest Guarantee Period, values developed from the Initial Premium Payment are illustrated using the Initial Guaranteed Interest Rate(s) declared by the insurance company, which include an additional first year only interest bonus credit of 0.75%. The interest rates will be guaranteed for the Initial Interest Guarantee Period, subject to an MVA. After the Initial Interest Guarantee Period, a new renewal interest rate will be declared annually, but can never be less than the Minimum Guaranteed Interest Rate shown.
- (4) **Account Value** is the amount you have at the end of each year if you leave your money in the contract until you start receiving annuity payments. It is also the amount available upon the Annuitant's death if it occurs before annuity payments begin. The death benefit is not affected by surrender charges or the MVA.
- (5) **Cash Surrender Value Before MVA** is the amount available at the end of each year if you surrender the contract (after deduction of any Surrender Charge) but before the application of any MVA. Surrender charges are applied to the Account Value according to the schedule below until the surrender charge period ends, which may be after the Initial Interest Guarantee Period has ended.

Years Measured from Premium Payment:	1	2	3	4	5	6	7	8+
Surrender Charges:	8%	7%	6%	5%	4%	3%	2%	0%

- (6) **Minimum Cash Surrender Value After MVA** is the minimum amount available at the end of each year if you surrender your contract before the end of five years, no matter what the MVA is. The minimum is set by law. The amount you receive may be higher or lower than the cash surrender value due to the application of the MVA, but never lower than this minimum. Otherwise the MVA works as follows: If the interest rate available on new contracts offered by the company is LOWER than your Initial Guaranteed Interest Rate, the MVA will INCREASE the amount you receive. If the interest rate available on new contracts offered by the company is HIGHER than your Initial Guaranteed Interest Rate, the MVA will DECREASE the amount you receive. Page 4 of this illustration provides additional information concerning the MVA.

Values Based on Assumption That Initial Guaranteed Rates Continue

- (7) **Interest Crediting Rates** are the same as in Column (3) for the Initial Interest Guarantee Period. After the Initial Interest Guarantee Period, a new renewal interest rate will be declared annually. For the purposes of calculating the values in this column, it is assumed that the Initial Guaranteed Interest Rate (without the bonus) will continue as the new renewal interest rate in all years. The actual renewal interest rates are not subject to an MVA and will very likely NOT be the same as the illustrated renewal interest rates.
- (8) **Account Value** is calculated the same way as Column (4).
- (9) **Cash Surrender Value Before and After MVA** is the Cash Surrender Value at the end of each year assuming that Initial Guaranteed Interest Rates continue, and that the continuing rates are the rates offered by the company on new contracts. In this case, the MVA would be zero, and Cash Surrender Values before and after the MVA would be the same.

Important Note: This illustration assumes you will take **no** withdrawals from your annuity before you begin to receive periodic income payments. **Withdrawals will reduce both the annuity Account Value and the Cash Surrender Value.** You may make partial withdrawals of up to 10% of your account value each contract year without paying surrender charges. Excess withdrawals (above 10%) and full withdrawals will be subject to surrender charges.

This illustration assumes the annuity's current interest crediting rates will not change. It is likely that they will change and actual values may be higher or lower than those in the illustration.

The values in this illustration are not guarantees or even estimates of the amounts you can expect from your annuity. For more information, read the annuity disclosure and annuity buyer's guide.

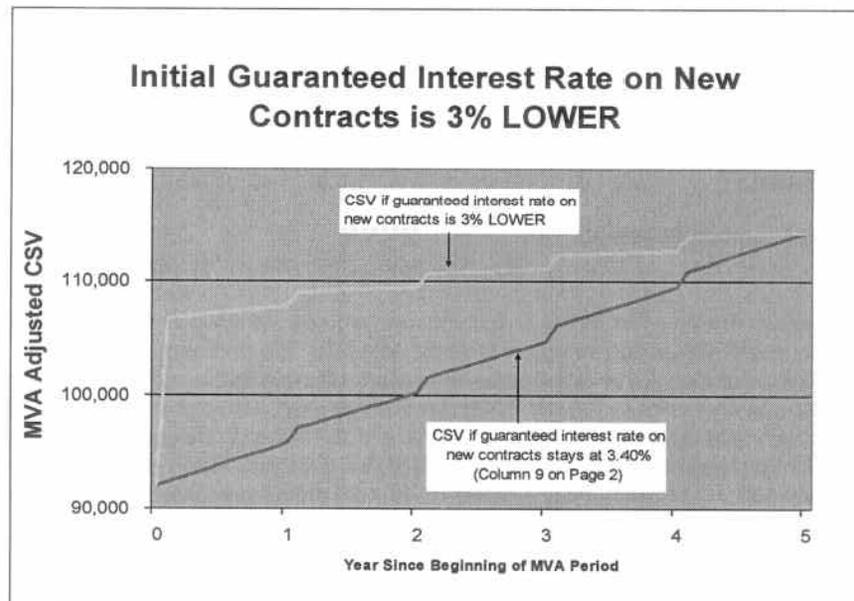
MVA-Adjusted Cash Surrender Values (CSVs) Under Sample Scenarios

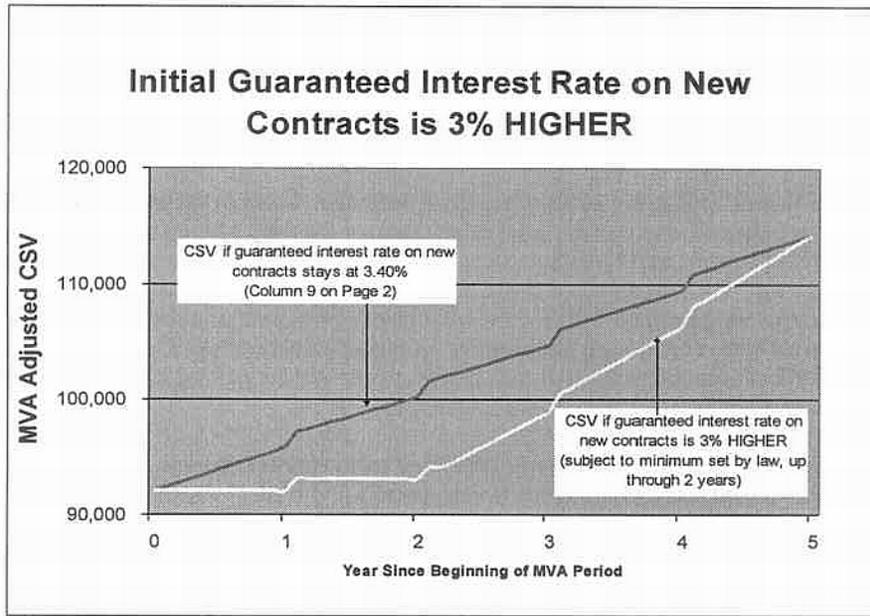
The graphs below* show MVA-adjusted Cash Surrender Values (CSVs) during the first five years of the contract, as illustrated on page 2 (\$100,000 single premium, a 5-year MVA Period) under two sample scenarios, as described below.

Graph #1 shows if the interest rate on new contracts is 3% LOWER than your Initial Guaranteed Interest Rate, the MVA will increase the amount you receive (green line). The pink line shows the Cash Surrender Values if the Initial Guaranteed Interest Rates continue (from Column (9) on Page 2).

Graph #2 shows if the interest rate on new contracts is 3% HIGHER than your Initial Guaranteed Interest Rate, the MVA will decrease the amount you receive, but not below the minimum set by law (Column (6) on Page 2), which in this scenario limits the decrease for the first 2 years (yellow line). The pink line shows the Cash Surrender Values if the Initial Guaranteed Interest Rates continue (from Column (9) on Page 2).

These graphs and the sample guaranteed interest rates on new contracts used are for demonstration purposes only and are not intended to be a projection of how guaranteed interest rates on new contracts are likely to behave.





*Color not reproducible in the Iowa Administrative Code.

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[ARC 0035C, IAB 3/7/12, effective 4/11/12]

APPENDIX VI

INSURANCE AGENT (PRODUCER) DISCLOSURE FOR ANNUITIES

Do Not Sign Unless You Have Read and Understand the Information in this Form

Date: _____

INSURANCE AGENT (PRODUCER) INFORMATION (“Me”, “I”, “My”)

First Name: _____ Last Name: _____

Business/Agency Name: _____ Website: _____

Business Mailing Address: _____

Business Telephone Number: _____

Email Address: _____

National Producer Number in [state]: _____

CUSTOMER INFORMATION (“You”, “Your”)

First Name: _____ Last Name: _____

What Types of Products Can I Sell You?

I am licensed to sell annuities to you in accordance with state law. If I recommend that You buy an annuity, it means I believe that it effectively meets Your financial situation, insurance needs, and financial objectives. Other financial products, such as life insurance or stocks, bonds and mutual funds, also may meet Your needs.

I offer the following products:

- Fixed or Fixed Indexed Annuities
- Variable Annuities
- Life Insurance

I need a separate license to provide advice about or to sell non-insurance financial products. I have checked below any non-insurance financial products that I am licensed and authorized to provide advice about or to sell.

- Mutual Funds
- Stocks/Bonds
- Certificates of Deposits

Whose Annuities Can I Sell to You?

I am authorized to sell:

<input type="checkbox"/> Annuities from Only One (1) Insurer	<input type="checkbox"/> Annuities from Two or More Insurers
<input type="checkbox"/> Annuities from Two or More Insurers although I primarily sell annuities from:	

How I’m Paid for My Work:

It’s important for You to understand how I’m paid for my work. Depending on the particular annuity You purchase, I may be paid a commission or a fee. Commissions are generally paid to Me by the insurance company while fees are generally paid to Me by the consumer. If You have questions about how I’m paid, please ask Me.

Depending on the particular annuity You buy, I will or may be paid cash compensation as follows:

Commission, which is usually paid by the insurance company or other sources. If other sources, describe: _____.

Fees (such as a fixed amount, an hourly rate, or a percentage of your payment), which are usually paid directly by the customer.

Other (Describe): _____.

If you have questions about the above compensation I will be paid for this transaction, please ask me.

I may also receive other indirect compensation resulting from this transaction (sometimes called “noncash” compensation), such as health or retirement benefits, office rent and support, or other incentives from the insurance company or other sources.

Drafting Note: *This disclosure may be adapted to fit the particular business model of the producer. As an example, if the producer only receives commission or only receives a fee from the consumer, the disclosure may be refined to fit that particular situation. This form is intended to provide an example of how to communicate producer compensation, but compliance with the regulation may also be achieved with more precise disclosure, including a written consulting, advising or financial planning agreement.*

Drafting Note: *The acknowledgment and signature should be in immediate proximity to the disclosure language.*

By signing below, you acknowledge that you have read and understand the information provided to you in this document.

Customer Signature

Date

Agent (Producer) Signature

Date

[ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

APPENDIX VII

CONSUMER REFUSAL TO PROVIDE INFORMATION**Do Not Sign Unless You Have Read and Understand the Information in this Form****Why are you being given this form?**

You're buying a financial product – an annuity.

To recommend a product that effectively meets your needs, objectives and situation, the agent, broker, or company needs information about you, your financial situation, insurance needs and financial objectives.

If you sign this form, it means you have not given the agent, broker, or company some or all the information needed to decide if the annuity effectively meets your needs, objectives and situation. You may lose protections under the Insurance Code of [this state] if you sign this form or provide inaccurate information.

Statement of Purchaser:

- I **REFUSE** to provide this information at this time.
- I have chosen to provide **LIMITED** information at this time.

Customer Signature

Date

[ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

APPENDIX VIII

Consumer Decision to Purchase an Annuity NOT Based on a Recommendation**Do Not Sign This Form Unless You Have Read and Understand It.****Why are you being given this form?**

You are buying a financial product – an annuity.

To recommend a product that effectively meets your needs, objectives and situation, the agent, broker, or company has the responsibility to learn about you, your financial situation, insurance needs and financial objectives.

If you sign this form, it means you know that you're buying an annuity that was not recommended.

Statement of Purchaser:

I understand that I am buying an annuity, but the agent, broker or company did not recommend that I buy it. If I buy it **without a recommendation**, I understand I may lose protections under the Insurance Code of [this state].

Customer Signature

Date

Agent/Producer Signature

Date

[ARC 5045C, IAB 6/3/20, effective 1/1/21; see correction note at end of chapter]

These rules are intended to implement Iowa Code chapters 507B and 522B.

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◊ Two or more ARCs

¹ The Administrative Rules Review Committee at their February 13, 1979, meeting delayed the effective date of rules 15.90 to 15.93 seventy days.

² Effective date (12/31/81) of rules 15.9 and 15.31 delayed 70 days by the Administrative Rules Review Committee.

³ At its meeting held August 13, 2003, the Administrative Rules Review Committee voted to delay the effective date of 15.43(10) until adjournment of the 2004 Session of the General Assembly.

⁴ The effective date of **ARC 5045C** was corrected to January 1, 2021, in the June 17, 2020, Iowa Administrative Bulletin.

ENVIRONMENTAL PROTECTION COMMISSION[567]

Former Water, Air and Waste Management[900], renamed by 1986 Iowa Acts, chapter 1245, Environmental Protection Commission under the “umbrella” of the Department of Natural Resources.

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CHAPTER 9
DELEGATION OF CONSTRUCTION PERMITTING AUTHORITY

[Prior subject matter DEQ Ch 24]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—9.1(455B) Scope. Iowa Code section 455B.183 delegates construction permitting authority over certain sewer and water main extensions to qualified local public works departments and rural water systems organized under Iowa Code chapter 357A or 504. This chapter describes the manner and criteria under which the department oversees this delegated authority.

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.2(455B,17A) Forms. The following forms are to be used by the local public works department or rural water system implementing this authority:

542-1001: Application for delegating permitting authority to local public works departments

542-1002: Statement of engineer's qualifications

542-1003: Review checklist for water main extensions at local public works departments

542-1004: Review checklist for sewer extensions

542-1005: Quarterly report for permitting authority

542-1057: Application for delegating permitting authority to rural water systems

542-1058: Review checklist for water main extensions at rural water systems

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.3(455B) Procedures. A local public works department or rural water system incorporated under Iowa Code chapter 357A or 504 exercising permitting authority for sewer or water supply distribution system extensions under Iowa Code section 455B.183 shall notify the director in writing prior to the first permit issuance, using Form 542-1001 or 542-1057, as applicable, and 542-1002. Additional information may be requested by the director.

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.4(455B) Criteria for permitting authority at local public works departments. The requirements for permitting authority at local public works departments are as follows:

9.4(1) Permitting authority under this rule applies only to extensions which:

a. Primarily serve residential consumers and will not result in an increase greater than 5 percent of the capacity of the treatment works or system, or will serve fewer than 250 dwelling units.

b. In the case of sewer extensions, will not exceed the capacity of any treatment works which received a federal or state monetary grant after 1972.

c. In the case of water main extensions, will not exceed the production capacity of any system constructed after 1972.

9.4(2) The local public works department's standard specifications must be in conformance with the Iowa Standards for Sewer Systems cited in 567—paragraph 64.2(9) "b," or the water supply construction standards in rule 567—43.3(455B), and must be filed with and approved by the department.

9.4(3) The reviewing engineer shall be licensed as a professional engineer in Iowa and shall be employed by the local public works department.

9.4(4) When reviewing applications for sewer and water supply distribution system extensions under its jurisdiction, the local public works department shall use the Iowa Standards for Sewer Systems, the water supply construction standards in rule 567—43.3(455B), and the local standard specifications approved by the department.

9.4(5) The local public works department shall use Form 542-1003 or Form 542-1004, as applicable, when reviewing plans. Upon issuance of each permit, the local public works department shall submit to the department a copy of the permit and a copy of the form used during the review.

9.4(6) The local public works department shall submit to the department a complete quarterly report using Form 542-1005 by the fifteenth day of the month following each quarter of the calendar year.

9.4(7) Plans for which a construction permit has been issued shall be retained on file by the local public works department for the life of the extension or until the extension has been platted.
[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.5(455B) Criteria for permitting authority at rural water systems. The requirements for permitting authority at rural water systems incorporated under Iowa Code chapter 357A or 504 are as follows:

9.5(1) Permitting authority under this rule applies only to extensions which:

a. Primarily serve residential consumers and will not result in an increase greater than 5 percent of the capacity of the treatment works or system, or will serve fewer than 250 dwelling units.

b. In the case of sewer extensions, will not exceed the capacity of any treatment works which received a federal or state monetary grant after 1972.

c. In the case of water main extensions, will not exceed the production capacity of any system constructed after 1972.

9.5(2) The rural water system's standard specifications must be in conformance with the Iowa Standards for Sewer Systems cited in 567—paragraph 64.2(9)“*b*,” or the water supply construction standards in 567—43.3(455B), and must be filed with and approved by the department. The system's hydraulic modeling must comply with the water supply distribution system standards pursuant to rule 567—43.3(455B).

9.5(3) The reviewing engineer shall be licensed as a professional engineer in Iowa and shall be employed or retained by the rural water system.

9.5(4) When reviewing applications for sewer and water supply distribution system extensions under its jurisdiction, the rural water system shall use the Iowa Standards for Sewer Systems, the water supply construction standards in rule 567—43.3(455B), and the local standard specifications approved by the department.

9.5(5) The rural water system shall use Form 542-1003 or Form 542-1058, as applicable, when reviewing plans. Upon issuance of each permit, the rural water system shall submit to the department a copy of the permit and a copy of the form used during the review.

9.5(6) The rural water system shall submit to the department a complete quarterly report using Form 542-1005 by the fifteenth day of the month following each quarter of the calendar year.

9.5(7) Plans for which a construction permit has been issued shall be retained on file by the rural water system for the life of the extension.

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.6(455B) No variance allowed. No variance to the design standards is allowed under delegated permitting authority. If a variance to the design standards is needed, the local public works department or rural water system must apply to the department for an individual construction permit following the wastewater permit procedures in rule 567—60.4(455B) and rule 567—64.2(455B) and the water supply permit procedures in 567—subrule 40.4(1).

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—9.7(455B) Criteria for rescission or revocation of delegated permitting authority.

9.7(1) The local public works department or rural water system may voluntarily request that its permitting authority be rescinded by submitting the request in writing to the director.

9.7(2) The director may suspend or revoke delegation of review and permit authority after notice and hearing as set forth in Iowa Code chapter 17A if the director determines that a public works department or rural water system with delegated permitting authority has approved extensions which do not comply with design criteria, which exceed the capacity of waste treatment plants or the production capacity of public water supply systems, or which otherwise violate state or federal requirements.

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

These rules are intended to implement Iowa Code sections 17A.3, 455B.105 and 455B.171 to 455B.187.

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TITLE II
AIR QUALITY

CHAPTER 20

SCOPE OF TITLE—DEFINITIONS

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—20.1(455B,17A) Scope of title. The department has jurisdiction over the atmosphere of the state to prevent, abate and control air pollution, by establishing standards for air quality and by regulating potential sources of air pollution through a system of general rules or specific permits. The construction and operation of any new or existing stationary source which emits or may emit any air pollutant requires a specific permit from the department, unless exempted by the department.

This chapter provides general definitions applicable to this title.

567—Chapter 21 contains the provisions requiring compliance schedules, allowing for variances, and setting forth the emission reduction program. 567—Chapter 22 contains the standards and procedures for the permitting of emission sources. 567—Chapter 23 contains the air emission standards for contaminants. 567—Chapter 24 provides for the reporting of excess emissions and the equipment maintenance and repair requirements. 567—Chapter 25 contains the testing and sampling requirements for new and existing sources. 567—Chapter 26 identifies air pollution emergency episodes and the preplanned abatement strategies. 567—Chapter 27 sets forth the conditions political subdivisions must meet in order to secure acceptance of a local air pollution control program. 567—Chapter 28 identifies the state ambient air quality standards. 567—Chapter 29 sets forth the qualifications for an observer for reading visible emissions. 567—Chapter 30 sets forth requirements to pay fees for specified activities. 567—Chapter 31 contains rules for the nonattainment major new source review (NSR) program and general conformity. 567—Chapter 32 specifies requirements for conducting the animal feeding operations field study. 567—Chapter 33 contains special regulations and construction permit requirements for major stationary sources and includes the requirements for prevention of significant deterioration (PSD). 567—Chapter 34 contains provisions for air quality emissions trading programs. 567—Chapter 35 specifies the requirements for the department to provide financial assistance to eligible applicants for the purpose of reducing air pollution emissions.

All dates specified in reference to the Code of Federal Regulations (CFR) are the dates of publication of the last amendments to the portion of the CFR being cited.

[ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17]

567—20.2(455B) Definitions. For the purpose of these rules, the following terms shall have the meaning indicated in this chapter. The definitions set out in Iowa Code section 455B.411 shall be considered to be incorporated verbatim in these rules.

“Air pollution alert” means that action condition declared when the concentrations of air contaminants reach the level at which the first stage control actions are to begin.

“Air pollution emergency” means that action condition declared when the air quality is continuing to degrade to a level that should never be reached, and that the most stringent control actions are necessary.

“Air pollution episode” means a combination of forecast or actual meteorological conditions and emissions of air contaminants which may or do present an imminent and substantial endangerment to the health of persons, during which the chief meteorological factors are the absence of winds that disperse air contaminants horizontally and a stable atmospheric layer which tends to inhibit vertical mixing through relatively deep layers.

“Air pollution forecast” means an air stagnation advisory issued to the department, the commission, and to appropriate air pollution control agencies by an authorized Air Stagnation Advisory Office of the National Weather Service predicting that meteorological conditions conducive to an air pollution episode may be imminent. This advisory may be followed by a prediction of the duration and termination of such meteorological conditions.

“*Air pollution warning*” means that action condition declared when the air quality is continuing to degrade from the levels classified as an air pollution alert, and where control actions in addition to those conducted under an air pollution alert are necessary.

“*Air quality standard*” means an allowable level of air contaminant or atmospheric air concentration established by the commission.

“*Ambient air*” means that portion of the atmosphere, external to buildings, to which the general public has access. Ambient air does not include the atmosphere over land owned or controlled by the source and to which public access is precluded by a fence or other physical barriers.

“*Anaerobic lagoon*,” for purposes of air quality rules contained in 567—Chapters 20 through 35, means an impoundment, the primary function of which is to store and stabilize organic wastes. The impoundment is designed to receive wastes on a regular basis and the design waste loading rates are such that the predominant biological activity in the impoundment will be anaerobic. An anaerobic lagoon does not include:

a. A runoff control basin which collects and stores only precipitation induced runoff from an open feedlot feeding operation; or

b. A waste slurry storage basin which receives waste discharges from confinement feeding operations and which is designed for complete removal of accumulated wastes from the basin at least semiannually; or

c. Any anaerobic treatment system which includes collection and treatment facilities for all off-gases.

“*ASME*” means the American Society of Mechanical Engineers.

“*ASTM*” means the American Society for Testing and Materials.

“*Auxiliary fuel firing equipment*” means equipment to supply additional heat, by the combustion of an auxiliary fuel, for the purpose of attaining temperatures sufficient to dry and ignite the waste material, to maintain ignition thereof, and to promote complete combustion of combustible gases, solids and vapors.

“*Backyard burning*” means the disposal of residential waste by open burning on the premises of the property where such waste is generated.

“*Biodiesel fuel*” means a renewable, biodegradable, mono alkyl ester combustible liquid fuel derived from agricultural plant oils or animal fat such as, but not limited to, soybean oil. For purposes of this definition, “biodiesel fuel” must also meet the specifications of American Society for Testing and Material Specifications (ASTM) D 6751-02, “Standard Specification for Biodiesel Fuel (B100) Blend Stock for Distillate Fuels,” and be registered with the U.S. Environmental Protection Agency as a fuel and a fuel additive under Section 211(b) of the Clean Air Act, 42 U.S.C. Sections 7401, et seq. as amended through November 15, 1990.

“*Btu*” means British thermal unit, the quantity of heat required to raise the temperature of one pound of water from 59°F to 60°F.

“*Carbonaceous fuel*” means any form of combustible matter (whether solid, liquid, vapor or gas) consisting primarily of carbon-containing compounds in either fixed or volatile form, and which is burned primarily for its heat content.

“*Chimney or stack*” means any flue, conduit or duct permitting the discharge or passage of air contaminants into the open air, or constructed or arranged for this purpose.

“*COH/1,000 linear feet*” means coefficient of haze per 1,000 linear feet, which is a measure of the optical density of a filtered deposit of particulate matter as given in ASTM Standard D-1704-61, and indicated by the following formula:

$$\text{COH/1,000 linear feet} = \frac{(\text{Area tape, ft}^2)(100,000)}{(\text{Volume of air sample, ft}^3)} \log \frac{100}{\% \text{ transmission}}$$

“*Combustion for indirect heating*” means the combustion of fuel to produce usable heat that is to be transferred through a heat-conducting materials barrier or by a heat storage medium to a material to

be heated so that the material being heated is not contacted by, and adds no substance to, the products of combustion.

“*Control equipment*” means any equipment that has the function to prevent the formation of or the emission to the atmosphere of air contaminants from any fuel burning, incinerator or process equipment.

“*Country grain elevator*” shall have the same definition as “country grain elevator” set forth in 567—subrule 22.10(1).

“*Criteria*” means information used as guidelines for decisions when establishing air quality goals, air quality standards and the various air quality levels, and which in no case is to be confused or used interchangeably with air quality goals or standards.

“*Diesel fuel*” means a low sulfur fuel oil that complies with the specifications for grade 1-D or 2-D, as defined by the American Society of Testing and Materials (ASTM) D 975-02, “Standard Specification for Diesel Fuel Oils,” grade 1-GT or 2-GT, as defined by ASTM D 2880-00, “Standard Specification for Gas Turbine Fuel Oils,” or grade 1 or 2, as defined by ASTM D 396-02, “Standard Specification for Fuel Oils.”

1. For purposes of the air quality rules contained in Title II, and unless otherwise specified, diesel fuel may contain a blend of up to 2.0 percent biodiesel fuel, by volume, as “biodiesel fuel” is defined in this rule.

2. The department shall consider air pollutant emissions calculations for the biodiesel fuel blends specified in numbered paragraph “1” to be equivalent to the air pollutant emissions calculations for unblended diesel fuel.

3. Construction permits or operating permits issued under 567—Chapter 22 which restrict equipment fuel use to diesel fuel shall be considered by the department to include the biodiesel fuel blends specified in numbered paragraph “1,” unless otherwise specified in 567—Chapter 22 or in a permit issued under 567—Chapter 22.

“*Director*” means the director of the department of natural resources or the director’s designee.

“*Electric furnace*” means a furnace in which the melting and refining of metals are accomplished by means of electrical energy.

“*Electronic format,*” “*electronic submittal,*” and “*electronic submittal format,*” for purposes of the rules in 567—Chapters 20 through 35, mean a software, Internet-based, or other electronic means specified by the department for submitting information or fees to the department related to, but not limited to, applications, certifications, determination requests, emissions inventories, forms, notifications, payments, permit applications and registrations. References to these information submittal methods in 567—Chapters 20 through 35 may, as specified by the department, include electronic submittal.

“*Emergency generator*” means any generator of which the sole function is to provide emergency backup power during an interruption of electrical power from the electric utility. An emergency generator does not include:

1. Peaking units at electric utilities; or
2. Generators at industrial facilities that typically operate at low rates, but are not confined to emergency purposes; or
3. Any standby generators that are used during time periods when power is available from the electric utility.

An emergency is an unforeseeable condition that is beyond the control of the owner or operator.

“*Emission limitation*” and “*emission standard*” mean a requirement established by a state, local government, or the administrator which limits the quantity, rate or concentration of emissions of air pollutants on a continuous basis, including any requirements which limit the level of opacity, prescribe equipment, set fuel specifications or prescribe operation or maintenance procedures for a source to ensure continuous emission reduction.

“*EPA conditional method*” means any method of sampling and analyzing for air pollutants that has been validated by the administrator but that has not been published as an EPA reference method.

“*EPA reference method*” means the following methods used for performance tests and continuous monitoring systems:

1. Performance test (stack test). A stack test shall be conducted according to EPA reference methods specified in 40 CFR 51, Appendix M (as amended through November 14, 2018); 40 CFR 60, Appendix A (as amended through November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through November 14, 2018).

2. Continuous monitoring systems. Minimum performance specifications and quality assurance procedures for performance evaluations of continuous monitoring systems are as specified in 40 CFR 60, Appendix B (as amended through November 14, 2018); 40 CFR 60, Appendix F (as amended through November 14, 2018); 40 CFR 75, Appendix A (as amended through August 30, 2016); 40 CFR 75, Appendix B (as amended through August 30, 2016); and 40 CFR 75, Appendix F (as amended through August 30, 2016).

“Equipment” means equipment capable of emitting air contaminants to produce air pollution such as fuel burning, combustion or process devices or apparatus including but not limited to fuel-burning equipment, refuse burning equipment used for the burning of fuel or other combustible material from which the products of combustion are emitted; and including but not limited to apparatus, equipment or process devices which generate heat and may emit products of combustion, and manufacturing, chemical, metallurgical or mechanical apparatus or process devices which may emit smoke, particulate matter or other air contaminants.

“Excess air” means that amount of air supplied in addition to the theoretical quantity necessary for complete combustion of all fuel or combustible waste material present.

“Excess emission” means any emission which exceeds any applicable emission standard prescribed in 567—Chapter 23 or rule 567—22.4(455B), 567—22.5(455B), 567—31.3(455B), or 567—33.3(455B) or any emission limit specified in a permit or order.

“Existing equipment” means equipment, machines, devices or installations that are in operation prior to September 23, 1970.

“Foundry cupola” means a stack-type furnace used for melting of metals consisting of, but not limited to, the furnace proper, tuyeres, fans or blowers, tapping spout, charging equipment, gas cleaning devices and other auxiliaries.

“Fugitive dust” means any airborne solid particulate matter emitted from any source other than a flue or stack.

“Garbage” means all solid and semisolid putrescible and nonputrescible animal and vegetable wastes resulting from the handling, preparing, cooking, storing and serving of food or of material intended for use as food, but excluding recognized industrial by-products.

“Gas cleaning device” means a facility designed to remove air contaminants from gases exhausted from equipment as defined herein.

“Goal” means a level of air quality which is expected to be obtained.

“Grain processing” means the equipment, or the combination of different types of equipment, used in the processing of grain to produce a product primarily for wholesale or retail sale for human or animal consumption, including the processing of grain for production of biofuels, except for “feed mill equipment,” as “feed mill equipment” is defined in rule 567—22.10(455B).

“Grain storage elevator” means any plant or installation at which grain is unloaded, handled, cleaned, dried, stored, or loaded and that is located at any wheat flour mill, wet corn mill, dry corn mill (human consumption), rice mill, or soybean oil extraction plant which has a permanent grain storage capacity (grain storage capacity which is inside a building, bin, or silo) of more than 35,200 m³ (ca. 1 million U.S. bushels).

“Greenhouse gas” means carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride.

“Heating value” means the heat released by combustion of one pound of waste or fuel measured in Btu on an as received basis. For solid fuels, the heating value shall be determined by use of ASTM Standard D2015-66.

“Incinerator” means a combustion apparatus designed for high temperature operation in which solid, semisolid, liquid or gaseous combustible refuse is ignited and burned efficiently, and from which the solid residues contain little or no combustible material.

“Initiation of construction, installation or alteration” means significant permanent modification of a site to install equipment, control equipment or permanent structures. Not included are activities incident to preliminary engineering, environmental studies, or acquisition of a site for a facility.

“Landscape waste” means any vegetable or plant wastes except garbage. The term includes trees, tree trimmings, branches, stumps, brush, weeds, leaves, grass, shrubbery and yard trimmings.

“Level” means a certain specified degree, quality or characteristic.

“Malfunction” means any sudden and unavoidable failure of control equipment or of a process to operate in a normal manner. Any failure that is caused entirely or in part by poor maintenance, careless operation, lack of an adequate maintenance program, or any other preventable upset condition or preventable equipment breakdown shall not be considered a malfunction.

“Maximum achievable control technology (MACT)” means the following regarding regulated hazardous air pollutant sources:

1. For existing sources, the emissions limitation reflecting the maximum degree of reduction in emissions that the administrator or the department, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable by sources in the category of stationary sources, that shall not be less stringent than the MACT floor.

2. For new sources, the emission limitation which is not less stringent than the emission limitation achieved in practice by the best-controlled similar source and which reflects the maximum degree of reduction in emissions that the administrator or the department, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable by the affected source.

“Maximum achievable control technology (MACT) floor” means the following:

1. For existing sources, the average emission limitation achieved by the best 12 percent of the existing sources in the United States (for which the administrator or the department has or could reasonably obtain emissions information), excluding those sources that have, within 18 months before the emission standard is proposed or within 30 months before such standard is promulgated, whichever is later, first achieved a level of emission rate or emission reduction which complies, or would comply if the source is not subject to such standard, with the lowest achievable emission rate applicable to the source category and prevailing at the time, for categories and subcategories of stationary sources with 30 or more sources in the category or subcategory, or the average emission limitation achieved by the best-performing five sources in the United States (for which the administrator or the department has or could reasonably obtain emissions information), for a category or subcategory of stationary sources with fewer than 30 sources in the category or subcategory.

2. For new sources, the emission limitation achieved in practice by the best-controlled similar source.

“New equipment” means except for any equipment or modified equipment to which 567—subrule 23.1(2) applies, any equipment or control equipment not under construction or for which components have not been purchased on or before September 23, 1970, and any equipment which is altered or modified after such date, which may cause the emission of air contaminants or eliminate, reduce or control the emission of air contaminants.

“Number 1 fuel oil” and *“number 2 fuel oil,”* also known as “distillate oil,” mean fuel oil that complies with the specifications for fuel oil number 1 or fuel oil number 2, as defined by the American Society of Testing and Materials (ASTM) D 396-02, “Standard Specification for Fuel Oils.”

1. For purposes of the air quality rules contained in Title II, and unless otherwise specified, number 1 fuel oil or number 2 fuel oil may contain a blend of up to 2.0 percent biodiesel fuel, by volume, as “biodiesel fuel” is defined in this rule.

2. The department shall consider air pollutant emissions calculations for the biodiesel fuel blends specified in numbered paragraph “1” to be equivalent to the air pollutant emissions calculations for unblended number 1 fuel oil or unblended number 2 fuel oil.

3. Construction permits or operating permits issued under 567—Chapter 22 which restrict equipment fuel use to number 1 fuel oil or number 2 fuel oil shall be considered by the department to

include the biodiesel fuel blends specified in numbered paragraph “1,” unless otherwise specified in 567—Chapter 22 or in a permit issued under 567—Chapter 22.

“*Objective*” means a certain specified degree, quality or characteristic expected to be attained.

“*Odor*” means that which produces a response of the human sense of smell to an odorous substance.

“*Odorous substance*” means a gaseous, liquid, or solid material that elicits a physiological response by the human sense of smell.

“*Odorous substance source*” means any equipment, installation operation, or material which emits odorous substances; such as, but not limited to, a stack, chimney, vent, window, opening, basin, lagoon, pond, open tank, storage pile, or inorganic or organic discharges.

“*One-hour period*” means any 60-minute period commencing on the hour.

“*Opacity*” means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background (See 567—Chapter 29).

“*Open burning*” means any burning of combustible materials where the products of combustion are emitted into the open air without passing through a chimney or stack.

“*Particulate matter*” (except for the purposes of new source performance standards as defined in 40 CFR 60) means any material, except uncombined water, that exists in a finely divided form as a liquid or solid at standard conditions and includes gaseous emissions that condense to liquid or solid form as measured by EPA-approved reference methods.

“*Parts per million (PPM)*” means a term which expresses the volumetric concentration of one material in one million unit volumes of a carrier material.

“*Plan documents*” means the reports, proposals, preliminary plans, survey and basis of design data, general and detail construction plans, profiles, specifications and all other information pertaining to equipment.

“*PM₁₀*” means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by an EPA-approved reference method.

“*PM_{2.5}*” means particulate matter as defined in this rule with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by an EPA-approved reference method.

“*Potential to emit*” means the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation is enforceable by the administrator. This term does not alter or affect the use of this term for any other purposes under the Act, or the term “capacity factor” as used in Title IV of the Act or the regulations relating to acid rain.

For the purpose of determining potential to emit for country grain elevators, the provisions set forth in 567—subrule 22.10(2) shall apply.

For purposes of calculating potential to emit for emergency generators, “maximum capacity” means one of the following:

1. 500 hours of operation annually, if the generator has actually been operated less than 500 hours per year for the past five years;
2. 8,760 hours of operation annually, if the generator has actually been operated more than 500 hours in one of the past five years; or
3. The number of hours specified in a state or federally enforceable limit.

If the source is subject to new source construction permit review, then potential to emit is defined as stated above or as established in a federally enforceable permit.

“*Privileged communication*” means information other than air pollutant emissions data the release of which would tend to affect adversely the competitive position of the owner or operator of the equipment.

“*Process*” means any action, operation or treatment, and all methods and forms of manufacturing or processing, that may emit smoke, particulate matter, gaseous matter or other air contaminant.

“*Process weight*” means the total weight of all materials introduced into any source operation. Solid fuels charged will be considered as part of the process weight, but liquid and gaseous fuels and combustion air will not.

“*Process weight rate*” means continuous or long-run steady-state source operations, the total process weight for the entire period of continuous operation or for a typical portion thereof, divided by the number of hours of such period or portion thereof; or for a cyclical or batch source operation, the total process weight for a period that covers a complete operation or an integral number of cycles, divided by the number of hours of actual process operation during such a period. Where the nature of any process or operation, or the design of any equipment is such as to permit more than one interpretation of this definition, the interpretation that results in the minimum value for allowable emission shall apply.

“*Refuse*” means garbage, rubbish and all other putrescible and nonputrescible wastes, except sewage and water-carried trade wastes.

“*Residential waste*” means any refuse generated on the premises as a result of residential activities. The term includes landscape waste grown on the premises or deposited thereon by the elements, but excludes garbage, tires, trade wastes, and any locally recyclable goods or plastics.

“*Rubbish*” means all waste materials of nonputrescible nature.

“*Salvage operations*” means any business, industry or trade engaged wholly or in part in salvaging or reclaiming any product or material, including, but not limited to, chemicals, drums, metals, motor vehicles or shipping containers.

“*Shutdown*” means the cessation of operation of any control equipment or process equipment or process for any purpose.

“*Six-minute period*” means any one of the ten equal parts of a one-hour period.

“*Smoke*” means gas-borne particles resulting from incomplete combustion, consisting predominantly, but not exclusively, of carbon, and other combustible material, or ash, that form a visible plume in the air.

“*Smoke monitor*” means a device using a light source and a light detector which can automatically measure and record the light-obscuring power of smoke at a specific location in the flue or stack of a source.

“*Source operation*” means the last operation preceding the emission of an air contaminant, and which results in the separation of the air contaminant from the process materials or in the conversion of the process materials into air contaminants, but is not an air pollution control operation.

“*Standard conditions*” means a temperature of 68°F and a pressure of 29.92 inches of mercury absolute.

“*Standard cubic foot (SCF)*” means the volume of one cubic foot of gas at standard conditions.

“*Standard metropolitan statistical area (SMSA)*” means an area which has at least one city with a population of at least 50,000 and such surrounding areas as geographically defined by the U.S. Bureau of the Budget (Department of Commerce).

“*Startup*” means the setting into operation of any control equipment or process equipment or process for any purpose.

“*Stationary source*” means any building, structure, facility or installation which emits or may emit any air pollutant.

“*Theoretical air*” means the exact amount of air required to supply the required oxygen for complete combustion of a given quantity of a specific fuel or waste.

“*Total suspended particulate*” means particulate matter as defined in this rule.

“*Trade waste*” means any refuse resulting from the prosecution of any trade, business, industry, commercial venture (including farming and ranching), or utility or service activity, and any governmental or institutional activity, whether or not for profit.

“*12-month rolling period*” means a period of 12 consecutive months determined on a rolling basis with a new 12-month period beginning on the first day of each calendar month.

“*Untreated*” as it refers to wood or wood products includes only wood or wood products that have not been treated with compounds such as, but not limited to, paint, pigment-stain, adhesive, varnish, lacquer, or resin or that have not been pressure treated with compounds such as, but not limited to, chromate copper acetate, pentachlorophenol or creosote. “*Untreated*” as it refers to seeds, pellets or other vegetative matter includes only seeds, pellets or other vegetative matter that has not been treated with pesticides or fungicides.

“*Urban area*” means any Iowa city of 100,000 or more population in the current census and all Iowa cities contiguous to such city.

“*Variance*” means a temporary waiver from rules or standards governing the quality, nature, duration or extent of emissions granted by the commission for a specified period of time.

“*Volatile organic compounds*” or “*VOC*” means any compound included in the definition of “volatile organic compounds” found at 40 CFR Section 51.100(s) as amended through November 28, 2018.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 0330C, IAB 9/19/12, effective 10/24/12; ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—20.3(455B) Air quality forms generally. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

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¹ Effective date of 20.2(455B), definition of “12-month rolling period,” delayed 70 days by the Administrative Rules Review Committee at its meeting held October 10, 1995; delay lifted by this Committee December 13, 1995, effective December 14, 1995.

CHAPTER 22
CONTROLLING POLLUTION

[Prior to 7/1/83, DEQ Ch 3]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—22.1(455B) Permits required for new or existing stationary sources.

22.1(1) Permit required. Unless exempted in subrule 22.1(2) or to meet the parameters established in paragraph “c” of this subrule, no person shall construct, install, reconstruct or alter any equipment, control equipment or anaerobic lagoon without first obtaining a construction permit, or permit pursuant to rule 567—22.8(455B), or permits required pursuant to rules 567—22.4(455B), 567—22.5(455B), 567—31.3(455B), and 567—33.3(455B) as required in this subrule. A permit shall be obtained prior to the initiation of construction, installation or alteration of any portion of the stationary source or anaerobic lagoon.

a. Existing sources. Sources built prior to September 23, 1970, are not subject to this subrule, unless they have been modified, reconstructed, or altered on or after September 23, 1970.

b. New or reconstructed major sources of hazardous air pollutants. No person shall construct or reconstruct a major source of hazardous air pollutants, as defined in 40 CFR 63.2 and 40 CFR 63.41 as adopted by reference in 567—subrule 23.1(4), unless a construction permit has been obtained from the department, which requires maximum achievable control technology for new sources to be applied. The permit shall be obtained prior to the initiation of construction or reconstruction of the major source.

c. New, reconstructed, or modified sources may initiate construction prior to issuance of the construction permit by the department if they meet the eligibility requirements stated in subparagraph (1) below. The applicant must assume any liability for construction conducted on a source before the permit is issued. In no case will the applicant be allowed to hook up the equipment to the exhaust stack or operate the equipment in any way that may emit any pollutant prior to receiving a construction permit.

(1) Eligibility.

1. The applicant has submitted a construction permit application to the department, as specified in subrule 22.1(3);

2. The applicant has notified the department of the applicant’s intentions in writing five working days prior to initiating construction; and

3. The source is not subject to rule 567—22.4(455B), 567—subrule 23.1(2), 567—subrule 23.1(3), 567—subrule 23.1(4), 567—subrule 23.1(5), rule 567—31.3(455B), or paragraph “b” of this subrule. Prevention of significant deterioration (PSD) provisions and prohibitions remain applicable until a proposed project legally obtains PSD synthetic minor status (i.e., obtains permitted limits which limit the source below the PSD thresholds).

(2) The applicant must cease construction if the department’s evaluation demonstrates that the construction, reconstruction or modification of the source will interfere with the attainment or maintenance of the national ambient air quality standards or will result in a violation of a control strategy required by 40 CFR Part 51, Subpart G, as amended through February 19, 2015.

(3) The applicant will be required to make any modification to the source that may be imposed in the issued construction permit.

(4) The applicant must notify the department of the date that construction or reconstruction actually started. All notifications shall be submitted to the department in writing no later than 30 days after construction or reconstruction started. All notifications shall include all of the information listed in 22.3(3) “b.”

d. Permit requirements for country grain elevators, country grain terminal elevators, grain terminal elevators, and feed mill equipment. The owner or operator of a country grain elevator, country grain terminal elevator, grain terminal elevator or feed mill equipment, as “country grain elevator,” “country grain terminal elevator,” “grain terminal elevator,” and “feed mill equipment” are defined in subrule 22.10(1), may elect to comply with the requirements specified in rule 567—22.10(455B) for equipment at these facilities.

22.1(2) Exemptions. The requirement to obtain a permit in subrule 22.1(1) is not required for the equipment, control equipment, and processes listed in this subrule. The permitting exemptions in this subrule do not relieve the owner or operator of any source from any obligation to comply with any other applicable requirements. Equipment, control equipment, or processes subject to rule 567—22.4(455B) and 567—Chapter 33 (except rule 567—33.9(455B)), prevention of significant deterioration requirements, or rule 567—22.5(455B) or 567—31.3(455B), requirements for nonattainment areas, may not use the exemptions from construction permitting listed in this subrule. Equipment, control equipment, or processes subject to 567—subrule 23.1(2), new source performance standards (40 CFR Part 60 NSPS); 567—subrule 23.1(3), emission standards for hazardous air pollutants (40 CFR Part 61 NESHAP); 567—subrule 23.1(4), emission standards for hazardous air pollutants for source categories (40 CFR Part 63 NESHAP); or 567—subrule 23.1(5), emission guidelines, may still use the exemptions from construction permitting listed in this subrule provided that a permit is not needed to create federally enforceable limits that restrict potential to emit. If equipment is permitted under the provisions of rule 567—22.8(455B), then no other exemptions shall apply to that equipment.

Records shall be kept at the facility for exemptions that have been claimed under the following paragraphs: 22.1(2)“a” (for equipment > 1 million Btu per hour input), 22.1(2)“b,” 22.1(2)“e,” 22.1(2)“r” or 22.1(2)“s.” The records shall contain the following information: the specific exemption claimed and a description of the associated equipment. These records shall be made available to the department upon request.

The following paragraphs are applicable to paragraphs 22.1(2)“g” and “i.” A facility claiming to be exempt under the provisions of paragraph 22.1(2)“g” or “i” shall provide to the department the information listed below. If the exemption is claimed for a source not yet constructed or modified, the information shall be provided to the department at least 30 days in advance of the beginning of construction on the project. If the exemption is claimed for a source that has already been constructed or modified and that does not have a construction permit for that construction or modification, the information listed below shall be provided to the department within 60 days of March 20, 1996. After that date, if the exemption is claimed by a source that has already been constructed or modified and that does not have a construction permit for that construction or modification, the source shall not operate until the information listed below is provided to the department:

- A detailed emissions estimate of the actual and potential emissions, specifically noting increases or decreases, for the project for all regulated pollutants (as defined in rule 567—22.100(455B)), accompanied by documentation of the basis for the emissions estimate;
 - A detailed description of each change being made;
 - The name and location of the facility;
 - The height of the emission point or stack and the height of the highest building within 50 feet;
 - The date for beginning actual construction and the date that operation will begin after the changes are made;
- A statement that the provisions of rules 567—22.4(455B), 567—22.5(455B), and 567—31.3(455B) and 567—Chapter 33 (except rule 567—33.9(455B)) do not apply; and
- A statement that the accumulated emissions increases associated with each change under paragraph 22.1(2)“i,” when totaled with other net emissions increases at the facility contemporaneous with the proposed change (occurring within five years before construction on the particular change commences), have not exceeded significant levels, as defined in 40 CFR 52.21(b)(23) as amended through October 20, 2010, and adopted in rules 567—22.4(455B) and 567—33.3(455B), and will not prevent the attainment or maintenance of the ambient air quality standards specified in 567—Chapter 28. This statement shall be accompanied by documentation for the basis of these statements.

The written statement shall contain certification by a responsible official as defined in rule 567—22.100(455B) of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

a. Fuel-burning equipment for indirect heating and reheating furnaces or cooling units using natural gas or liquefied petroleum gas with a capacity of less than ten million Btu per hour input per combustion unit.

b. Fuel-burning equipment for indirect heating or indirect cooling with a capacity of less than 1 million Btu per hour input per combustion unit when burning untreated wood, untreated seeds or pellets, other untreated vegetative materials, or fuel oil, provided that the equipment and the fuel meet the conditions specified in this paragraph. Used oils meeting the specification from 40 CFR 279.11 as amended through July 14, 2006, are acceptable fuels for this exemption. When combusting used oils, the equipment must have a maximum rated capacity of 50,000 Btu or less per hour of heat input or a maximum throughput of 3,600 gallons or less of used oils per year. When combusting untreated wood, untreated seeds or pellets, or other untreated vegetative materials, the equipment must have a maximum rated capacity of 265,600 Btu or less per hour or a maximum throughput of 378,000 pounds or less per year of each fuel or any combination of fuels. Records shall be maintained on site by the owner or operator for at least two calendar years to demonstrate that fuel usage is less than the exemption thresholds. Owners or operators initiating construction, installation, reconstruction, or alteration of equipment (as defined in rule 567—20.2(455B)) on or before October 23, 2013, burning coal, used oils, untreated wood, untreated seeds or pellets, or other untreated vegetative materials that qualified for this exemption may continue to claim this exemption after October 23, 2013, without being restricted to the maximum heat input or throughput specified in this paragraph.

c. Mobile internal combustion and jet engines, marine vessels and locomotives.

d. Equipment used for cultivating land, harvesting crops, or raising livestock other than anaerobic lagoons. This exemption is not applicable if the equipment is used to remove substances from grain which were applied to the grain by another person. This exemption is also not applicable to equipment used by a person to manufacture commercial feed, as defined in Iowa Code section 198.3, which is normally not fed to livestock, owned by the person or another person, in a feedlot, as defined in Iowa Code section 172D.1(6), or a confinement building owned or operated by that person and located in this state.

e. Incinerators and pyrolysis cleaning furnaces with a rated refuse burning capacity of less than 25 pounds per hour for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013. Pyrolysis cleaning furnace exemption is limited to those units that use only natural gas or propane. Salt bath units are not included in this exemption. Incinerators or pyrolysis cleaning furnaces for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall not qualify for this exemption. After October 23, 2013, only paint clean-off ovens with a maximum rated capacity of less than 25 pounds per hour that do not combust lead-containing materials shall qualify for this exemption.

f. Fugitive dust controls unless a control efficiency can be assigned to the equipment or control equipment.

g. Equipment or control equipment which reduces or eliminates all emission to the atmosphere. If a source wishes to obtain credit for emission reductions, a permit must be obtained for the reduction prior to the time the reduction is made. If a construction permit has been previously issued for the equipment or control equipment, all other conditions of the construction permit remain in effect.

h. Equipment (other than anaerobic lagoons) or control equipment which emits odors unless such equipment or control equipment also emits particulate matter, or any other regulated air contaminant (as defined in rule 567—22.100(455B)).

i. Initiation of construction, installation, reconstruction, or alteration (modification) to equipment (as defined in rule 567—20.2(455B)) on or before October 23, 2013, which will not result in a net emissions increase (as defined in 567—subrule 31.3(1)) of more than 1.0 lb/hr of any regulated air pollutant (as defined in rule 567—22.100(455B)). Emission reduction achieved through the installation of control equipment, for which a construction permit has not been obtained, does not establish a limit to potential emissions.

Hazardous air pollutants (as defined in rule 567—22.100(455B)) are not included in this exemption except for those listed in Table 1. Further, the net emissions rate INCREASE must not equal or exceed the values listed in Table 1.

Table 1

Pollutant	Ton/year
Lead	0.6
Asbestos	0.007
Beryllium	0.0004
Vinyl Chloride	1
Fluorides	3

This exemption is ONLY applicable to vertical discharges with the exhaust stack height 10 or more feet above the highest building within 50 feet. If a construction permit has been previously issued for the equipment or control equipment, the conditions of the construction permit remain in effect. In order to use this exemption, the facility must comply with the information submission to the department as described above.

The department reserves the right to require proof that the expected emissions from the source which is being exempted from the air quality construction permit requirement, in conjunction with all other emissions, will not prevent the attainment or maintenance of the ambient air quality standards specified in 567—Chapter 28. If the department finds, at any time after a change has been made pursuant to this exemption, evidence of violations of any of the department's rules, the department may require the source to submit to the department sufficient information to determine whether enforcement action should be taken. This information may include, but is not limited to, any information that would have been submitted in an application for a construction permit for any changes made by the source under this exemption, and air quality dispersion modeling.

Equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall not qualify for this exemption.

j. Residential heaters, cookstoves, or fireplaces, which burn untreated wood, untreated seeds or pellets, or other untreated vegetative materials.

k. Asbestos demolition and renovation projects subject to 40 CFR 61.145 as amended through January 16, 1991.

l. The equipment in laboratories used exclusively for nonproduction chemical and physical analyses. Nonproduction analyses means analyses incidental to the production of a good or service and includes analyses conducted for quality assurance or quality control activities, or for the assessment of environmental impact.

m. Storage tanks with a capacity of less than 19,812 gallons and an annual throughput of less than 200,000 gallons.

n. Stack or vents to prevent escape of sewer gases through plumbing traps. Systems which include any industrial waste are not exempt.

o. A nonproduction surface coating process that uses only hand-held aerosol spray cans.

p. Brazing, soldering or welding equipment or portable cutting torches used only for nonproduction activities.

q. Cooling and ventilating equipment: Comfort air conditioning not designed or used to remove air contaminants generated by, or released from, specific units of equipment.

r. An internal combustion engine with a brake horsepower rating of less than 400 measured at the shaft, provided that the owner or operator meets all of the conditions in this paragraph. For the purposes of this exemption, the manufacturer's nameplate rated capacity at full load shall be defined as the brake horsepower output at the shaft. The owner or operator of an engine that was manufactured, ordered, modified or reconstructed after March 18, 2009, may use this exemption only if the owner or operator, prior to installing, modifying or reconstructing the engine, submits to the department a

completed registration on forms provided by the department (unless the engine is exempted from registration, as specified in this paragraph or on the registration form), certifying that the engine is in compliance with the following federal regulations:

- (1) New source performance standards (NSPS) for stationary compression ignition internal combustion engines (40 CFR Part 60, Subpart IIII); or
- (2) New source performance standards (NSPS) for stationary spark ignition internal combustion engines (40 CFR Part 60, Subpart JJJJ); and
- (3) National emission standards for hazardous air pollutants (NESHAP) for reciprocating internal combustion engines (40 CFR Part 63, Subpart ZZZZ).

Use of this exemption does not relieve an owner or operator from any obligation to comply with NSPS or NESHAP requirements. An engine that meets the definition of a nonroad engine as specified in 40 CFR 1068.30 is exempt from the registration requirements of this paragraph (22.1(2) “r”).

s. Equipment that is not related to the production of goods or services and used exclusively for academic purposes, located at educational institutions (as defined in Iowa Code section 455B.161). The equipment covered under this exemption is limited to: lab hoods, art class equipment, wood shop equipment in classrooms, wood fired pottery kilns, and fuel-burning units with a capacity of less than one million Btu per hour fuel capacity. This exemption does not apply to incinerators.

t. Any container, storage tank, or vessel that contains a fluid having a maximum true vapor pressure of less than 0.75 psia. “Maximum true vapor pressure” means the equilibrium partial pressure of the material considering:

- For material stored at ambient temperature, the maximum monthly average temperature as reported by the National Weather Service, or
- For material stored above or below the ambient temperature, the temperature equal to the highest calendar-month average of the material storage temperature.

u. Equipment for carving, cutting, routing, turning, drilling, machining, sawing, surface grinding, sanding, planing, buffing, sandblast cleaning, shot blasting, shot peening, or polishing ceramic artwork, leather, metals (other than beryllium), plastics, concrete, rubber, paper stock, and wood or wood products, where such equipment is either used for nonproduction activities or exhausted inside a building.

v. Manually operated equipment, as defined in rule 567—22.100(455B), used for buffing, polishing, carving, cutting, drilling, machining, routing, sanding, sawing, scarfing, surface grinding, or turning.

w. Small unit exemption.

(1) “Small unit” means any emission unit and associated control (if applicable) that emits less than the following:

1. 2 pounds per year of lead and lead compounds expressed as lead (40 pounds per year of lead or lead compounds for equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013);
2. 5 tons per year of sulfur dioxide;
3. 5 tons per year of nitrogen oxides;
4. 5 tons per year of volatile organic compounds;
5. 5 tons per year of carbon monoxide;
6. 5 tons per year of particulate matter (particulate matter as defined in 40 CFR Part 51.100(pp));
7. 2.5 tons per year of PM₁₀;
8. 0.52 tons per year of PM_{2.5} (does not apply to equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013); and
9. 5 tons per year of hazardous air pollutants (as defined in rule 567—22.100(455B)).

For the purposes of this exemption, “emission unit” means any part or activity of a stationary source that emits or has the potential to emit any pollutant subject to regulation under the Act. This exemption applies to existing and new or modified “small units.”

An emission unit that emits hazardous air pollutants (as defined in rule 567—22.100(455B)) is not eligible for this exemption if the emission unit is required to be reviewed for compliance with

567—subrule 23.1(3), emission standards for hazardous air pollutants (40 CFR 61, NESHAP), or 567—subrule 23.1(4), emission standards for hazardous air pollutants for source categories (40 CFR 63, NESHAP).

An emission unit that emits air pollutants that are not regulated air pollutants as defined in rule 567—22.100(455B) shall not be eligible to use this exemption.

(2) Permit requested. If requested in writing by the owner or operator of a small unit, the director may issue a construction permit for the emission point associated with that emission unit.

(3) An owner or operator that utilizes the small unit exemption must maintain on site an “exemption justification document.” The exemption justification document must document conformance and compliance with the emission rate limits contained in the definition of “small unit” for the particular emission unit or group of similar emission units obtaining the exemption. Controls which may be part of the exemption justification document include, but are not limited to, the following: emission control devices, such as cyclones, filters, or baghouses; restricted hours of operation or fuel; and raw material or solvent substitution. The exemption justification document for an emission unit or group of similar emission units must be made available for review during normal business hours and for state or EPA on-site inspections, and shall be provided to the director or the director’s representative upon request. If an exemption justification document does not exist, the applicability of the small unit exemption is voided for that particular emission unit or group of similar emission units. The controls described in the exemption justification document establish a limit on the potential emissions. An exemption justification document shall include the following for each applicable emission unit or group of similar emission units:

1. A narrative description of how the emissions from the emission unit or group of similar emission units were determined and maintained at or below the annual small unit exemption levels.

2. If air pollution control equipment is used, a description of the air pollution control equipment used on the emission unit or group of similar emission units and a statement that the emission unit or group of similar emission units will not be operated without the pollution control equipment operating.

3. If air pollution control equipment is used, applicant shall maintain a copy of any report of manufacturer’s testing results of any emissions test, if available. The department may require a test if it believes that a test is necessary for the exemption claim.

4. A description of all production limits required for the emission unit or group of similar emission units to comply with the exemption levels.

5. Detailed calculations of emissions reflecting the use of any air pollution control devices or production or throughput limitations, or both, for applicable emission unit or group of similar emission units.

6. Records of actual operation that demonstrate that the annual emissions from the emission unit or group of similar emission units were maintained below the exemption levels.

7. Facilities designated as major sources with respect to rules 567—22.4(455B) and 567—22.101(455B), or subject to any applicable federal requirements, shall retain all records demonstrating compliance with the exemption justification document for five years. The record retention requirements supersede any retention conditions of an individual exemption.

8. A certification from the responsible official that the emission unit or group of similar emission units have complied with the exemption levels specified in 22.1(2) “w”(1).

(4) Requirement to apply for a construction permit. An owner or operator of a small unit will be required to obtain a construction permit or take the unit out of service if the emission unit exceeds the small unit emission levels.

1. If, during an inspection or other investigation of a facility, the department believes that the emission unit exceeds the emission levels that define a “small unit,” then the department will submit calculations and detailed information in a letter to the owner or operator. The owner or operator shall have 60 days to respond with detailed calculations and information to substantiate a claim that the small unit does not exceed the emission levels that define a small unit.

2. If the owner or operator is unable to substantiate a claim to the satisfaction of the department, then the owner or operator that has been using the small unit exemption must cease operation of that small

unit or apply for a construction permit for that unit within 90 days after receiving a letter of notice from the department. The emission unit and control equipment may continue operation during this period and the associated initial application review period.

3. If the notification of nonqualification as a small unit is made by the department following the process described above, the owner or operator will be deemed to have constructed an emission unit without the required permit and may be subject to applicable penalties.

(5) Required notice for construction or modification of a “substantial small unit.” The owner or operator shall notify the department in writing at least 10 days prior to commencing construction of any new or modified “substantial small unit” as defined in 22.1(2) “w”(6). The owner or operator shall notify the department within 30 days after determining an existing small unit meets the criteria of the “substantial small unit” as defined in 22.1(2) “w”(6). Notification shall include the name of the business, the location where the unit will be installed, and information describing the unit and quantifying its emissions. The owner or operator shall notify the department within 90 days of the end of the calendar year for which the aggregate emissions from substantial small units at the facility have reached any of the cumulative notice thresholds listed below.

(6) For the purposes of this paragraph, “substantial small unit” means a small unit which emits more than the following amounts, as documented in the exemption justification document:

1. 2 pounds per year of lead and lead compounds expressed as lead (30 pounds per year of lead or lead compounds for equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013);

2. 3.75 tons per year of sulfur dioxide;

3. 3.75 tons per year of nitrogen oxides;

4. 3.75 tons per year of volatile organic compounds;

5. 3.75 tons per year of carbon monoxide;

6. 3.75 tons per year of particulate matter (particulate matter as defined in 40 CFR Part 51.100(pp));

7. 1.875 tons per year of PM₁₀;

8. 0.4 tons per year of PM_{2.5} (does not apply to equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013); or

9. 3.75 tons per year of any hazardous air pollutant or 3.75 tons per year of any combination of hazardous air pollutants.

An emission unit is a “substantial small unit” only for those substances for which annual emissions exceed the above-indicated amounts.

(7) Required notice that a cumulative notice threshold has been reached. Once a “cumulative notice threshold,” as defined in 22.1(2) “w”(8), has been reached for any of the listed pollutants, the owner or operator at the facility must apply for air construction permits for all substantial small units for which the cumulative notice threshold for the pollutant(s) in question has been reached. The owner or operator shall have 90 days from the date it determines that the cumulative notice threshold has been reached in which to apply for construction permit(s). The owner or operator shall submit a letter to the department, within 5 working days of making this determination, establishing the date the owner or operator determined that the cumulative notice threshold had been reached.

(8) “Cumulative notice threshold” means the total combined emissions from all substantial small units using the small unit exemption which emit at the facility the following amounts, as documented in the exemption justification document:

1. 0.6 tons per year of lead and lead compounds expressed as lead;

2. 40 tons per year of sulfur dioxide;

3. 40 tons per year of nitrogen oxides;

4. 40 tons per year of volatile organic compounds;

5. 100 tons per year of carbon monoxide;

6. 25 tons per year of particulate matter (particulate matter as defined in 40 CFR Part 51.100(pp));

7. 15 tons per year of PM₁₀;

8. 10 tons per year of PM_{2.5} (does not apply to equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013); or

9. 10 tons per year of any hazardous air pollutant or 25 tons per year of any combination of hazardous air pollutants.

x. The following equipment, processes, and activities:

(1) Cafeterias, kitchens, and other facilities used for preparing food or beverages primarily for consumption at the source.

(2) Consumer use of office equipment and products, not including printers or businesses primarily involved in photographic reproduction.

(3) Janitorial services and consumer use of janitorial products.

(4) Internal combustion engines used for lawn care, landscaping, and groundskeeping purposes.

(5) Laundry activities located at a stationary source that uses washers and dryers to clean, with water solutions of bleach or detergents, or to dry clothing, bedding, and other fabric items used on site. This exemption does not include laundry activities that use dry cleaning equipment or steam boilers.

(6) Bathroom vent emissions, including toilet vent emissions.

(7) Blacksmith forges.

(8) Plant maintenance and upkeep activities and repair or maintenance shop activities (e.g., groundskeeping, general repairs, cleaning, painting, welding, plumbing, retarring roofs, installing insulation, and paving parking lots), provided that these activities are not conducted as part of manufacturing process, are not related to the source's primary business activity, and do not otherwise trigger a permit modification. Cleaning and painting activities qualify if they are not subject to control requirements for volatile organic compounds or hazardous air pollutants as defined in rule 567—22.100(455B).

(9) Air compressors and vacuum pumps, including hand tools.

(10) Batteries and battery charging stations, except at battery manufacturing plants.

(11) Equipment used to store, mix, pump, handle or package soaps, detergents, surfactants, waxes, glycerin, vegetable oils, greases, animal fats, sweetener, corn syrup, and aqueous salt or caustic solutions, provided that appropriate lids and covers are utilized and that no organic solvent has been mixed with such materials.

(12) Equipment used exclusively to slaughter animals, but not including other equipment at slaughterhouses, such as rendering cookers, boilers, heating plants, incinerators, and electrical power generating equipment.

(13) Vents from continuous emissions monitors and other analyzers.

(14) Natural gas pressure regulator vents, excluding venting at oil and gas production facilities.

(15) Equipment used by surface coating operations that apply the coating by brush, roller, or dipping, except equipment that emits volatile organic compounds or hazardous air pollutants as defined in rule 567—22.100(455B).

(16) Hydraulic and hydrostatic testing equipment.

(17) Environmental chambers not using gases which are hazardous air pollutants as defined in rule 567—22.100(455B).

(18) Shock chambers, humidity chambers, and solar simulators.

(19) Fugitive dust emissions related to movement of passenger vehicles on unpaved road surfaces, provided that the emissions are not counted for applicability purposes and that any fugitive dust control plan or its equivalent is submitted as required by the department.

(20) Process water filtration systems and demineralizers, demineralized water tanks, and demineralizer vents.

(21) Boiler water treatment operations, not including cooling towers or lime silos.

(22) Oxygen scavenging (deaeration) of water.

(23) Fire suppression systems.

(24) Emergency road flares.

(25) Steam vents, safety relief valves, and steam leaks.

(26) Steam sterilizers.

(27) Application of hot melt adhesives from closed-pot systems using polyolefin compounds, polyamides, acrylics, ethylene vinyl acetate and urethane material when stored and applied at the manufacturer's recommended temperatures. Equipment used to apply hot melt adhesives shall have a safety device that automatically shuts down the equipment if the hot melt temperature exceeds the manufacturer's recommended application temperature.

y. Direct-fired equipment burning natural gas, propane, or liquefied propane with a capacity of less than 10 million Btu per hour input, and direct-fired equipment burning fuel oil with a capacity of less than 1 million Btu per hour input, with emissions that are attributable only to the products of combustion. Emissions other than those attributable to the products of combustion shall be accounted for in an enforceable permit condition or shall otherwise be exempt under this subrule.

z. Closed refrigeration systems, including storage tanks used in refrigeration systems, but excluding any combustion equipment associated with such systems.

aa. Pretreatment application processes that use aqueous-based chemistries designed to clean a substrate, provided that the chemical concentrate contains no more than 5 percent organic solvents by weight. This exemption includes pretreatment processes that use aqueous-based cleaners, cleaner-phosphatizers, and phosphate conversion coating chemistries.

bb. Indoor-vented powder coating operations with filters or powder recovery systems.

cc. Electric curing ovens or curing ovens that run on natural gas or propane with a maximum heat input of less than 10 million Btu per hour and that are used for powder coating operations, provided that the total cured powder usage is less than 75 tons of powder per year at the stationary source. Records shall be maintained on site by the owner or operator for a period of at least two calendar years to demonstrate that cured powder usage is less than the exemption threshold.

dd. Each production painting, adhesive or coating unit using an application method other than a spray system and associated cleaning operations that use 1,000 gallons or less of coating and solvents annually, unless the production painting, adhesive or coating unit and associated cleaning operations are subject to work practice, process limits, emissions limits, stack testing, record-keeping or reporting requirements under 567—subrule 23.1(2), 567—subrule 23.1(3), or 567—subrule 23.1(4). Records shall be maintained on site by the owner or operator for a period of at least two calendar years to demonstrate that paint, adhesive, or solvent usage is at or below the exemption threshold.

ee. Any production surface coating activity that uses only nonrefillable hand-held aerosol cans, where the total volatile organic compound emissions from all these activities at a stationary source do not exceed 5.0 tons per year.

ff. Production welding.

(1) Consumable electrode.

1. Welding operations for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013, using a consumable electrode, provided that the consumable electrode used falls within American Welding Society specification A5.18/A5.18M for Gas Metal Arc Welding (GMAW), A5.1 or A5.5 for Shielded Metal Arc Welding (SMAW), and A5.20 for Flux Core Arc Welding (FCAW), and provided that the quantity of all electrodes used at the stationary source of the acceptable specifications is below 200,000 pounds per year for GMAW and 28,000 pounds per year for SMAW or FCAW. Records that identify the type and annual amount of welding electrode used shall be maintained on site by the owner or operator for a period of at least two calendar years. For stationary sources where electrode usage exceeds these levels, the welding activity at the stationary source may be exempted if the amount of electrode used (Y) is less than:

Y = the greater of $1380x - 19,200$ or 200,000 for GMAW, or

Y = the greater of $187x - 2,600$ or 28,000 for SMAW or FCAW

Where "x" is the minimum distance to the property line in feet and "Y" is the annual electrode usage in pounds per year.

If the stationary source has welding processes that fit into both of the specified exemptions, the most stringent limits must be applied.

2. Welding operations for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, using a consumable electrode, provided that the consumable electrode used falls within American Welding Society specification A5.18/A5.18M for Gas Metal Arc Welding (GMAW), A5.1 or A5.5 for Shielded Metal Arc Welding (SMAW), and A5.20 for Flux Core Arc Welding (FCAW), and provided that the quantity of all electrodes used at the stationary source of the acceptable specifications is below 12,500 pounds per year for GMAW and 1,600 pounds per year for SMAW or FCAW. Records that identify the type and annual amount of welding electrode used shall be maintained on site by the owner or operator for a period of at least two calendar years. For stationary sources where electrode usage exceeds these levels, the welding activity at the stationary source may be exempted if the amount of electrode used (Y) is less than:

Y = the greater of $84x - 1,200$ or 12,500 for GMAW, or

Y = the greater of $11x - 160$ or 1,600 for SMAW or FCAW

Where “x” is the minimum distance to the property line in feet and “Y” is the annual electrode usage in pounds per year.

If the stationary source has welding processes that fit into both of the specified exemptions, the most stringent limits must be applied.

(2) Resistance welding, submerged arc welding, or arc welding that does not use a consumable electrode, provided that the base metals do not include stainless steel, alloys of lead, alloys of arsenic, or alloys of beryllium and provided that the base metals are uncoated, excluding manufacturing process lubricants.

gg. Electric hand soldering, wave soldering, and electric solder paste reflow ovens for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013. Electric hand soldering, wave soldering, and electric solder paste reflow ovens for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall be limited to 37,000 pounds or less per year of lead-containing solder. Records shall be maintained on site by the owner or operator for at least two calendar years to demonstrate that use of lead-containing solder is less than the exemption thresholds.

hh. Pressurized piping and storage systems for natural gas, propane, liquefied petroleum gas (LPG), and refrigerants, where emissions could only result from an upset condition.

ii. Emissions from the storage and mixing of paints and solvents associated with the painting operations, provided that the emissions from the storage and mixing are accounted for in an enforceable permit condition or are otherwise exempt.

jj. Product labeling using laser and ink-jet printers with target distances less than or equal to six inches and an annual material throughput of less than 1,000 gallons per year as calculated on a stationary sourcewide basis.

kk. Equipment related to research and development activities at a stationary source, provided that:

(1) Actual emissions from all research and development activities at the stationary source based on a 12-month rolling total are less than the following levels:

2 pounds per year of lead and lead compounds expressed as lead (40 pounds per year for research and development activities that commenced on or before October 23, 2013);

5 tons per year of sulfur dioxide;

5 tons per year of nitrogen oxides;

5 tons per year of volatile organic compounds;

5 tons per year of carbon monoxide;

5 tons per year of particulate matter (particulate matter as defined in 40 CFR Part 51.100(pp) as amended through November 29, 2004);

2.5 tons per year of PM_{10} ;

0.52 tons per year of $PM_{2.5}$ (does not apply to research and development activities that commenced on or before October 23, 2013); and

5 tons per year of hazardous pollutants (as defined in rule 567—22.100(455B)); and

(2) The owner or operator maintains records of actual operations demonstrating that the annual emissions from all research and development activities conducted under this exemption are below the levels listed in subparagraph (1) above. These records shall:

1. Include a list of equipment that is included under the exemption;
2. Include records of actual operation and detailed calculations of actual annual emissions, reflecting the use of any control equipment and demonstrating that the emissions are below the levels specified in the exemption;
3. Include, if air pollution equipment is used in the calculation of emissions, a copy of any report of manufacturer's testing, if available. The department may require a test if it believes that a test is necessary for the exemption claim; and
4. Be maintained on site for a minimum of two years, be made available for review during normal business hours and for state and EPA on-site inspections, and be provided to the director or the director's designee upon request. Facilities designated as major sources pursuant to rules 567—22.4(455B) and 567—22.101(455B), or subject to any applicable federal requirements, shall retain all records demonstrating compliance with this exemption for five years.

(3) An owner or operator using this exemption obtains a construction permit or ceases operation of equipment if operation of the equipment would cause the emission levels listed in this exemption to be exceeded.

For the purposes of this exemption, "research and development activities" shall be defined as activities:

1. That are operated under the close supervision of technically trained personnel; and
2. That are conducted for the primary purpose of theoretical research or research and development into new or improved processes and products; and
3. That do not manufacture more than de minimis amounts of commercial products; and
4. That do not contribute to the manufacture of commercial products by collocated sources in more than a de minimis manner.

ll. A regional collection center (RCC), as defined in 567—Chapter 211, involved in the processing of permitted hazardous materials from households and conditionally exempt small quantity generators (CESQG), not to exceed 1,200,000 pounds of VOC containing material in a 12-month rolling period. Latex paint drying may not exceed 120,000 pounds per year on a 12-month rolling total. Other nonprocessing emission units (e.g., standby generators and waste oil heaters) shall not be eligible to use this exemption.

mm. Cold solvent cleaning machines that are not in-line cleaning machines, where the maximum vapor pressure of the solvents used shall not exceed 0.7 kPa (5 mmHg or 0.1 psi) at 20°C (68°F). The machine must be equipped with a tightly fitted cover or lid that shall be closed at all times except during parts entry and removal. This exemption cannot be used for cold solvent cleaning machines that use solvent containing methylene chloride (CAS # 75-09-2), perchloroethylene (CAS # 127-18-4), trichloroethylene (CAS # 79-01-6), 1,1,1-trichloroethane (CAS # 71-55-6), carbon tetrachloride (CAS # 56-23-5) or chloroform (CAS # 67-66-3), or any combination of these halogenated HAP solvents in a total concentration greater than 5 percent by weight.

nn. Emissions from mobile over-the-road trucks, and mobile agricultural and construction internal combustion engines that are operated only for repair or maintenance purposes at equipment repair shops or equipment dealerships, and only when the repair shops or equipment dealerships are not major sources as defined in rule 567—22.100(455B).

oo. A non-road diesel fueled engine, as defined in 40 CFR 1068.30 as amended through April 30, 2010, with a brake horsepower rating of less than 1,100 at full load measured at the shaft, used to conduct periodic testing and maintenance on natural gas pipelines. For the purposes of this exemption, the manufacturer's nameplate rating shall be defined as the brake horsepower output at the shaft at full load.

(1) To qualify for the exemption, the engine must:

1. Be used for periodic testing and maintenance on natural gas pipelines outside the compressor station, which shall not exceed 330 hours in any 12-month consecutive period at a single location; or

2. Be used for periodic testing and maintenance on natural gas pipelines within the compressor station, which shall not exceed 330 hours in any 12-month consecutive period.

(2) The owner or operator shall maintain a monthly record of the number of hours the engine operated and a record of the rolling 12-month total of the number of hours the engine operated for each location outside the compressor station and within the compressor station. These records shall be maintained for two years. Records shall be made available to the department upon request.

(3) This exemption shall not apply to the replacement or substitution of engines for backup power generation at a pipeline compressor station.

22.1(3) Construction permits. The owner or operator of a new or modified stationary source shall apply for a construction permit. One copy of a construction permit application for a new or modified stationary source shall be presented or mailed to the air quality bureau of the department of natural resources. Alternatively, the owner or operator may apply for a construction permit for a new or modified stationary source through the electronic submittal format specified by the department. References to “application(s),” “certification(s),” “determination request(s),” “emissions inventory(ies),” “fees,” “form(s),” “notification(s),” “payment(s),” “permit application(s),” and “registration(s)” in rules 567—22.1(455B) through 567—22.10(455B) may, as specified by the department, include electronic submittal. An owner or operator applying for a permit as required pursuant to rule 567—31.3(455B) (nonattainment new source review) or rule 567—33.3(455B) (prevention of significant deterioration (PSD)) shall present or mail to the department one hard copy of a construction permit application to the address specified above and, upon request from the department, shall also submit one electronic copy and one additional hard copy of the application. Application submission methods may include, but are not limited to, U.S. Postal Service, private parcel delivery services, and hand delivery. Applications are not required to be submitted by certified mail. The owner or operator of any new or modified industrial anaerobic lagoon shall apply for a construction permit as specified in this subrule and as provided in 567—Chapter 22. The owner or operator of a new or modified anaerobic lagoon for an animal feeding operation shall apply for a construction permit as provided in 567—Chapter 65.

a. Regulatory applicability determinations. If requested in writing, the director will review the design concepts of equipment and associated control equipment prior to application for a construction permit. The purpose of the review would be to determine the acceptability of the location of the equipment. If the review is requested, the requester shall supply the following information and submit a fee as required in 567—Chapter 30:

- (1) Preliminary plans and specifications of equipment and related control equipment.
- (2) The exact site location and a plot plan of the immediate area, including the distance to and height of nearby buildings and the estimated location and elevation of the emission points.
- (3) The estimated emission rates of any air contaminants which are to be considered.
- (4) The estimated exhaust gas temperature, velocity at the point of discharge, and stack diameter at the point of discharge.
- (5) An estimate of when construction would begin and when construction would be completed.

b. Construction permit applications. Each application for a construction permit shall be submitted to the department on the permit application forms available on the department’s website. Final plans and specifications for the proposed equipment or related control equipment shall be submitted with the application for a permit and shall be prepared by or under the direct supervision of a professional engineer licensed in the state of Iowa in conformance with Iowa Code section 542B.1, or consistent with the provisions of Iowa Code section 542B.26 for any full-time employee of any corporation while the employee is doing work for that corporation. The application for a permit to construct shall include the following information:

- (1) A description of the equipment or control equipment covered by the application;
- (2) A scaled plot plan, including the distance and height of nearby buildings, and the location and elevation of existing and proposed emission points;
- (3) The composition of the effluent stream, both before and after any control equipment with estimates of emission rates, concentration, volume and temperature;
- (4) The physical and chemical characteristics of the air contaminants;

(5) The proposed dates and description of any tests to be made by the owner or operator of the completed installation to verify compliance with applicable emission limits or standards of performance;

(6) Information pertaining to sampling port locations, scaffolding, power sources for operation of appropriate sampling instruments, and pertinent allied facilities for making tests to ascertain compliance;

(7) Any additional information deemed necessary by the department to determine compliance with or applicability of rules 567—22.4(455B), 567—22.5(455B), 567—31.3(455B) and 567—33.3(455B);

(8) Application for a case-by-case MACT determination. If the source meets the definition of construction or reconstruction of a major source of hazardous air pollutants, as defined in paragraph 22.1(1)“b,” then the owner or operator shall submit an application for a case-by-case MACT determination, as required in 567—subparagraph 23.1(4)“b”(1), with the construction permit application. In addition to this paragraph, an application for a case-by-case MACT determination shall include the following information:

1. The hazardous air pollutants (HAP) emitted by the constructed or reconstructed major source, and the estimated emission rate for each HAP, to the extent this information is needed by the permitting authority to determine MACT;

2. Any federally enforceable emission limitations applicable to the constructed or reconstructed major source;

3. The maximum and expected utilization of capacity of the constructed or reconstructed major source, and the associated uncontrolled emission rates for that source, to the extent this information is needed by the permitting authority to determine MACT;

4. The controlled emissions for the constructed or reconstructed major source in tons/yr at expected and maximum utilization of capacity to the extent this information is needed by the permitting authority to determine MACT;

5. A recommended emission limitation for the constructed or reconstructed major source consistent with the principles set forth in 40 CFR Part 63.43(d) as amended through December 27, 1996;

6. The selected control technology to meet the recommended MACT emission limitation, including technical information on the design, operation, size, estimated control efficiency of the control technology (and the manufacturer’s name, address, telephone number, and relevant specifications and drawings, if requested by the permitting authority);

7. Supporting documentation including identification of alternative control technologies considered by the applicant to meet the emission limitation, and analysis of cost and non-air quality health environmental impacts or energy requirements for the selected control technology;

8. An identification of any listed source category or categories in which the major source is included;

(9) A signed statement that ensures the applicant’s legal entitlement to install and operate equipment covered by the permit application on the property identified in the permit application. A signed statement shall not be required for rock crushers, portable concrete or asphalt equipment used in conjunction with specific identified construction projects which are intended to be located at a site only for the duration of the specific, identified construction project;

(10) Application fee.

1. The owner or operator shall submit a fee as required in 567—Chapter 30 to obtain a permit under subrule 22.1(1), rule 567—22.4(455B), rule 567—22.5(455B), rule 567—22.8(455B), rule 567—22.10(455B), 567—Chapter 31 or 567—Chapter 33;

2. For application submittals from a minor source as defined in 567—Chapter 30, the department shall not initiate review and processing of a permit application submittal until all required application fees have been paid to the department; and

(11) Quantity of greenhouse gas emissions for all applications for projects that will or do have greenhouse gas emissions. For all applications for projects that will not or do not have greenhouse gas emissions, the applicant shall indicate in the application that no greenhouse gases will be emitted, and the applicant will not be required to file an inventory of greenhouse gases with that application, unless requested by the department.

c. Application requirements for anaerobic lagoons. The application for a permit to construct an anaerobic lagoon shall include the following information:

- (1) The source of the water being discharged to the lagoon;
- (2) A plot plan, including distances to nearby residences or occupied buildings, local land use zoning maps of the vicinity, and a general description of the topography in the vicinity of the lagoon;
- (3) In the case of an animal feeding operation, the information required in rule 567—65.15(455B);
- (4) In the case of an industrial source, a chemical description of the waste being discharged to the lagoon;
- (5) A report of sulfate analyses conducted on the water to be used for any purpose in a livestock operation proposing to use an anaerobic lagoon. The report shall be prepared by using standard methods as defined in 567—60.2(455B);
- (6) A description of available water supplies to prove that adequate water is available for dilution;
- (7) In the case of an animal feeding operation, a waste management plan describing the method of waste collection and disposal and the land to be used for disposal. Evidence that the waste disposal equipment is of sufficient size to dispose of the wastes within a 20-day period per year shall also be provided;
- (8) Any additional information needed by the department to determine compliance with these rules.

22.1(4) Conditional permits. Rescinded IAB 3/18/15, effective 4/22/15.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 7565B, IAB 2/11/09, effective 3/18/09; ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 1013C, IAB 9/18/13, effective 10/23/13; ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3440C, IAB 11/8/17, effective 12/13/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—22.2(455B) Processing permit applications.

22.2(1) Incomplete applications. The department will notify the applicant whether the application is complete or incomplete. If the application is found by the department to be incomplete upon receipt, the applicant will be notified within 30 days of that fact and of the specific deficiencies. Sixty days following such notification, the application may be denied for lack of information. When this schedule would cause undue hardship to an applicant, or the applicant has a compelling need to proceed promptly with the proposed installation, modification or location, a request for priority consideration and the justification therefor shall be submitted to the department.

22.2(2) Public notice and participation. A notice of intent to issue a construction permit to a major stationary source shall be published by the department in a newspaper having general circulation in the area affected by the emissions of the proposed source. The notice and supporting documentation shall be made available for public inspection upon request from the department's central office. Publication of the notice shall be made at least 30 days prior to issuing a permit and shall include the department's evaluation of ambient air impacts. The public may submit written comments or request a public hearing. If the response indicates significant interest, a public hearing may be held after due notice.

22.2(3) Final notice. The department shall notify the applicant in writing of the issuance or denial of a construction permit as soon as practicable and at least within 120 days of receipt of the completed application. This shall not apply to applicants for electric generating facilities subject to Iowa Code chapter 476A.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 1913C, IAB 3/18/15, effective 4/22/15]

567—22.3(455B) Issuing permits.

22.3(1) Stationary sources other than anaerobic lagoons. In no case shall a construction permit which results in an increase in emissions be issued to any facility which is in violation of any condition found in a permit involving PSD, NSPS, NESHAP or a provision of the Iowa state implementation plan. If the facility is in compliance with a schedule for correcting the violation and that schedule is contained in an order or permit condition, the department may consider issuance of a construction permit. A

construction permit shall be issued when the director concludes that the preceding requirement has been met and:

a. That the required plans and specifications represent equipment which reasonably can be expected to comply with all applicable emission standards, and

b. That the expected emissions from the proposed source or modification in conjunction with all other emissions will not prevent the attainment or maintenance of the ambient air quality standards specified in 567—Chapter 28, and

c. That the applicant has not relied on emission limits based on stack height that exceeds good engineering practice or any other dispersion techniques as defined in 567—subrule 23.1(6), and

d. That the applicant has met all other applicable requirements.

22.3(2) Anaerobic lagoons. A construction permit for an industrial anaerobic lagoon shall be issued when the director concludes that the application for permit represents an approach to odor control that can reasonably be expected to comply with the criteria in 567—subrule 23.5(2). A construction permit for an animal feeding operation using an anaerobic lagoon shall be issued when the director concludes that the application has met the requirements of rule 567—65.15(455B).

22.3(3) Conditions of approval. A permit may be issued subject to conditions which shall be specified in writing. Such conditions may include but are not limited to emission limits, operating conditions, fuel specifications, compliance testing, continuous monitoring, and excess emission reporting.

a. Each permit shall specify the date on which it becomes void if work on the installation for which it was issued has not been initiated.

b. Each permit shall list the requirements for notifying the department of the dates of intended startup, start of construction and actual equipment startup. All notifications shall be in writing and include the following information:

- (1) The date or dates required by 22.3(3) “*b*” for which the notice is being submitted.
- (2) Facility name.
- (3) Facility address.
- (4) DNR facility number.
- (5) DNR air construction permit number.
- (6) The name or the number of the emission unit or units in the notification.
- (7) The emission point number or numbers in the notification.
- (8) The name and signature of a company official.
- (9) The date the notification was signed.

c. Each permit shall specify that no review has been undertaken on the various engineering aspects of the equipment other than the potential of the equipment for reducing air contaminant emissions.

d. Rescinded IAB 3/18/15, effective 4/22/15.

e. If changes in the final plans and specifications are proposed by the permittee after a construction permit has been issued, a supplemental permit shall be obtained.

f. A permit is not transferable from one location to another or from one piece of equipment to another unless the equipment is portable. When portable equipment for which a permit has been issued is to be transferred from one location to another, the department shall be notified in writing at least 7 days prior to the transfer of the portable equipment to the new location. Written notification shall be submitted to the department through one of the following methods: electronic mail (email), mail delivery service (including U.S. Mail), hand delivery, facsimile (fax), or by electronic format specified by the department (at such time as an Internet-based submittal system or other, similar electronic submittal system becomes available). However, if the owner or operator is relocating the portable equipment to an area currently classified as nonattainment for ambient air quality standards or to an area under a maintenance plan for ambient air quality standards, the owner or operator shall notify the department at least 14 days prior to transferring the portable equipment to the new location. A list of nonattainment and maintenance areas may be obtained from the department, upon request, or on the department’s Internet website. The owner or operator will be notified by the department at least 10 days prior to the scheduled relocation if said relocation will prevent the attainment or maintenance of ambient air quality standards and thus require a

more stringent emission standard and the installation of additional control equipment. In such a case, the owner or operator shall obtain a supplemental permit prior to the initiation of construction, installation, or alteration of such additional control equipment.

g. The issuance of a permit (approval to construct) shall not relieve any owner or operator of the responsibility to comply fully with applicable provisions of the state implementation plan and any other requirement under local, state or federal law.

22.3(4) Denial of a permit.

a. When an application for a construction permit is denied, the applicant shall be notified in writing of the reasons therefor. A denial shall be without prejudice to the right of the applicant to file a further application after revisions are made to meet the objections specified as reasons for the denial.

b. The department may deny an application based upon the applicant's failure to provide a signed statement of the applicant's legal entitlement to install and operate equipment covered by the permit application on the property identified in the permit application.

22.3(5) Modification of a permit. The director may, after public notice of such decision, modify a condition of approval of an existing permit for a major stationary source or an emission limit contained in an existing permit for a major stationary source if necessary to attain or maintain an ambient air quality standard, or to mitigate excessive deposition of mercury.

22.3(6) Limits on hazardous air pollutants. The department may limit a source's hazardous air pollutant potential to emit, as defined at rule 567—22.100(455B), in the source's construction permit for the purpose of establishing federally enforceable limits on the source's hazardous air pollutant potential to emit.

22.3(7) Revocation of a permit. The department may revoke a permit upon obtaining knowledge that a permit holder has lost legal entitlement to use the property identified in the permit to install and operate equipment covered by the permit, upon notice that the property owner does not wish to have continued the operation of the permitted equipment, or upon notice that the owner of the permitted equipment no longer wishes to retain the permit for future operation.

22.3(8) Ownership change of permitted equipment. The new owner shall notify the department in writing no later than 30 days after the change in ownership of equipment covered by a construction permit pursuant to rule 567—22.1(455B). The notification to the department shall be mailed to the Air Quality Bureau, Iowa Department of Natural Resources, 502 East 9th Street, Des Moines, Iowa 50319, and shall include the following information:

- a. The date of ownership change;
- b. The name, address and telephone number of the responsible official, the contact person and the owner of the equipment both before and after ownership change; and
- c. The construction permit number of the equipment changing ownership.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 0330C, IAB 9/19/12, effective 10/24/12; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 4335C, IAB 3/13/19, effective 4/17/19]

567—22.4(455B) Special requirements for major stationary sources located in areas designated attainment or unclassified (PSD). As applicable, the owner or operator of a stationary source shall comply with the rules for prevention of significant deterioration (PSD) as set forth in 567—Chapter 33. An owner or operator required to apply for a construction permit under this rule shall submit all required fees as required in 567—Chapter 30.

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—22.5(455B) Special requirements for nonattainment areas. As applicable, the owner or operator of a stationary source shall comply with the requirements for the nonattainment major NSR program as set forth in rule 567—31.20(455B). An owner or operator required to apply for a construction permit under this rule shall submit all required fees as required in 567—Chapter 30.

[ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—22.6(455B) Nonattainment area designations. Rescinded **ARC 1227C**, IAB 12/11/13, effective 1/15/14.

567—22.7(455B) Alternative emission control program.

22.7(1) Applicability. The owner or operator of any source located in an area with attainment or unclassified status (as published at 40 CFR §81.316 amended August 5, 2013) or located in an area with an approved state implementation plan (SIP) demonstrating attainment by the statutory deadline may apply for an alternative set of emission limits if:

a. The applicant is presently in compliance with EPA approved SIP requirements, or
b. The applicant is subject to a consent order to meet an EPA approved compliance schedule and the final compliance date will not be delayed by the use of alternative emission limits.

22.7(2) Demonstration requirements. The applicant for the alternative emission control program shall have the burden of demonstrating that:

a. The alternative emission control program will not interfere with the attainment and maintenance of ambient air quality standards, including the reasonable further progress or prevention of significant deterioration requirements of the Clean Air Act;

b. The alternative emission limits are equivalent to existing emission limits in pollution reduction, enforceability, and environmental impact; (In the case of a particulate nonattainment area, the difference between the allowable emission rate and the actual emission rate, as of January 1, 1978, cannot be credited in the emissions tradeoff.)

c. The pollutants being exchanged are comparable and within the same pollutant category;

d. Hazardous air pollutants designated in 40 CFR Part 61, as amended through July 20, 2004, will not be exchanged for nonhazardous air pollutants;

e. The alternative program will not result in any delay in compliance by any source.

Specific situations may require additional demonstration as specified at 44 FR 71780-71788, December 11, 1979, or as requested by the director.

22.7(3) Approval process.

a. The director shall review all alternative emission control program proposals and shall make recommendations on all completed demonstrations to the commission.

b. After receiving recommendations from the director and public comments made available through the hearing process, the commission may approve or disapprove the alternative emission control program proposal.

c. If approved by the commission, the program will be forwarded to the EPA regional administrator as a revision to the State Implementation Plan. The alternative emission control program must receive the approval of the EPA regional administrator prior to becoming effective.

[**ARC 1227C**, IAB 12/11/13, effective 1/15/14]

567—22.8(455B) Permit by rule.

22.8(1) Permit by rule for spray booths. Spray booths which comply with the requirements contained in this rule will be deemed to be in compliance with the requirements to obtain an air construction permit and an air operating permit. Spray booths which comply with this rule will be considered to have federally enforceable limits so that their potential emissions are less than the major source limits for regulated air pollutants and hazardous air pollutants as defined in rule 567—22.100(455B). An owner or operator required to apply for a permit by rule under this subrule shall submit fees as required in 567—Chapter 30.

a. Definition. “Sprayed material” is material applied by spray equipment when used in a surface coating process in a spray booth, including but not limited to paint, solvents, and mixtures of paint and solvents. Powder coatings applied in an indoor-vented spray booth equipped with filters or overspray powder recovery systems are not considered sprayed material for purposes of this rule (567—22.8(455B)).

b. Facilities which facilitywide spray one gallon per day or less of sprayed material are exempt from all other requirements in 567—Chapter 22, except that they must submit the certification in

22.8(1) “e” to the department and keep records of daily sprayed material use. Any spray booth or associated equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall use sprayed material with a maximum lead content of 0.35 pounds or less per gallon if the booth or associated equipment is subject to the following NESHAP: 40 CFR Part 63, Subpart HHHHHH or Subpart XXXXXX. Any spray booth or associated equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, that is not subject to the NESHAP or is otherwise exempt from the NESHAP shall use sprayed material with a maximum lead content of 0.02 pounds or less per gallon. The owner or operator must keep the records of daily sprayed material use for 18 months from the date to which the records apply and shall keep safety data sheets (SDS) or equivalent records for at least two calendar years to demonstrate that the sprayed materials contain lead at less than the exemption thresholds. The owner or operator must also certify that the facility is in compliance with or otherwise exempt from the federal regulations specified in 22.8(1) “e.”

c. Facilities which facilitywide spray more than one gallon per day but never more than three gallons per day are exempt from all other requirements in 567—Chapter 22, except that they must submit the certification in 22.8(1) “e” to the department, keep records of daily sprayed material use, and vent emissions from a spray booth(s) through a stack(s) which is at least 22 feet tall, measured from ground level. Any spray booth or associated equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall use sprayed material with a maximum lead content of 0.35 pounds or less per gallon if the booth or associated equipment is subject to the following NESHAP: 40 CFR Part 63, Subpart HHHHHH or Subpart XXXXXX. Any spray booth or associated equipment for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, that is not subject to the NESHAP or is otherwise exempt from the NESHAP shall use sprayed material with a maximum lead content of 0.02 pounds or less per gallon. The owner or operator must keep the records of daily sprayed material use for 18 months from the date to which the records apply and shall keep safety data sheets (SDS) or equivalent records for at least two calendar years to demonstrate that the sprayed materials contain lead at less than the exemption thresholds. The owner or operator must also certify that the facility is in compliance with or otherwise exempt from the federal regulations specified in 22.8(1) “e.”

d. Facilities which facilitywide spray more than three gallons per day are not eligible to use the permit by rule for spray booths and must apply for a construction permit as required by subrules 22.1(1) and 22.1(3) unless otherwise exempt.

e. Notification letter.

(1) Facilities which claim to be permitted by provisions of this rule must submit to the department a written notification letter, on forms provided by the department, certifying that the facility meets the following conditions:

1. All paint booths and associated equipment are in compliance with the provisions of subrule 22.8(1);

2. All paint booths and associated equipment are in compliance with all applicable requirements including, but not limited to, the allowable particulate emission rate for painting and surface coating operations of 0.01 gr/scf of exhaust gas as specified in 567—subrule 23.4(13); and

3. All paint booths and associated equipment currently are or will be in compliance with or otherwise exempt from the national emissions standards for hazardous air pollutants (NESHAP) for paint stripping and miscellaneous surface coating at area sources (40 CFR Part 63, Subpart HHHHHH) and the NESHAP for metal fabricating and finishing at area sources (40 CFR Part 63, Subpart XXXXXX) by the applicable NESHAP compliance dates.

(2) The certification must be signed by one of the following individuals:

1. For corporations, a principal executive officer of at least the level of vice president, or a responsible official as defined at rule 567—22.100(455B).

2. For partnerships, a general partner.

3. For sole proprietorships, the proprietor.

4. For municipal, state, county, or other public facilities, the principal executive officer or the ranking elected official.

22.8(2) Reserved.

[**ARC 7565B**, IAB 2/11/09, effective 3/18/09; **ARC 8215B**, IAB 10/7/09, effective 11/11/09; **ARC 1013C**, IAB 9/18/13, effective 10/23/13; **ARC 2352C**, IAB 1/6/16, effective 12/16/15; **ARC 3679C**, IAB 3/14/18, effective 4/18/18]

567—22.9(455B) Special requirements for visibility protection.

22.9(1) Definitions. Definitions included in this subrule apply to the provisions set forth in rule 567—22.9(455B).

“*Best available retrofit technology (BART)*” means an emission limitation based on the degree of reduction achievable through the application of the best system of continuous emission reduction for each pollutant which is emitted by an existing stationary facility. The emission limitation must be established, on a case-by-case basis, taking into consideration the technology available, the costs of compliance, the energy and non-air quality environmental impacts of compliance, any pollution control equipment in use or in existence at the source, the remaining useful life of the source, and the degree of improvement in visibility which may reasonably be anticipated to result from the use of such technology.

“*Deciview*” means a haze index derived from calculated light extinction, such that uniform changes in haziness correspond to uniform incremental changes in perception across the entire range of conditions, from pristine to highly impaired. The deciview haze index is calculated based on an equation found in 40 CFR 51.301, as amended on July 1, 1999.

“*Mandatory Class I area*” means any Class I area listed in 40 CFR Part 81, Subpart D, as amended through October 5, 1989.

22.9(2) Best available retrofit technology (BART) applicability. A source shall comply with the provisions of subrule 22.9(3) if the source falls within numbers 1 through 20 or 22 through 26 of the “stationary source categories” of air pollutants listed in rule 22.100(455B) or is a fossil-fuel fired boiler individually totaling more than 250 million Btu’s per hour heat input and meets the following criteria:

- a. Any emission unit for which startup began after August 7, 1962; and
- b. Construction of the emission unit commenced on or before August 7, 1977; and
- c. The sum of the potential to emit, as “potential to emit” is defined in 567—20.2(455B), from emission units identified above is equal to or greater than 250 tons per year or more of one of the following pollutants: nitrogen oxides, sulfur dioxide, particulate matter (PM₁₀), or volatile organic compounds.

22.9(3) Duty to self-identify. The owner or operator or designated representative of a facility meeting the conditions of subrule 22.9(2) shall submit two copies of a completed BART Eligibility Certification Form #542-8125, which shall include all information necessary for the department to complete eligibility determinations. The information submitted shall include source identification, description of processes, potential emissions, emission unit and emission point characteristics, date construction commenced and date of startup, and other information required by the department. The completed form was required to be submitted to the Air Quality Bureau, Department of Natural Resources, by September 1, 2005.

22.9(4) Notification. The department shall notify in writing the owner or operator or designated representative of a source of the department’s determination that either:

- a. A source meets the conditions listed in 22.9(2) (a source that meets these conditions is BART-eligible); or
- b. For the purposes of the regional haze program, a source may cause or contribute to visibility impairment in any mandatory Class I area, as identified during either:
 - (1) Regional haze plan development required by 40 CFR 51.308(d) as amended on July 6, 2005; or
 - (2) A five-year periodic review on the progress toward the reasonable progress goals required by 40 CFR 51.308(g) as amended on July 6, 2005; or
 - (3) A ten-year comprehensive periodic revision of the implementation plan required by 40 CFR 51.308(f) as amended on July 6, 2005.

22.9(5) Analysis. The department may request in writing an analysis from the owner or operator or designated representative of a source that the department has determined may be causing or contributing to visibility impairment in a mandatory Class I area.

a. BART control analysis. For the purposes of BART, a source that is responsible for an impact of 1.0 deciview or more at a mandatory Class I area is considered to cause visibility impairment. A source that is responsible for an impact of 0.5 deciview or more at a mandatory Class I area is considered to contribute to visibility impairment. If a source meets either of these criteria, the owner or operator or designated representative shall prepare the BART analysis in accordance with Section IV of Appendix Y of 40 CFR Part 51 as amended through July 5, 2005, and shall submit the BART analysis 180 days after receipt of written notification by the department that a BART analysis is required.

b. Regional haze analysis. The owner or operator or designated representative of a source subject to 22.9(4)“b” shall prepare and submit an analysis after receipt of written notification by the department that an analysis is required.

22.9(6) Control technology implementation. Following the department’s review of the analysis submitted pursuant to 22.9(5), an owner or operator of a source identified in 22.9(4) shall:

a. Submit all necessary permit applications to achieve the emissions requirements established following the completion of analysis performed in accordance with 22.9(5).

b. Install, operate, and maintain the control technology as required by permits issued by the department.

22.9(7) BART exemption. The owner or operator of a source subject to the BART emission control requirements may apply for an exemption from subrule 22.9(5) in accordance with 40 CFR 51.303 as amended on July 1, 1999.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 4335C, IAB 3/13/19, effective 4/17/19]

567—22.10(455B) Permitting requirements for country grain elevators, country grain terminal elevators, grain terminal elevators and feed mill equipment. The requirements of this rule apply only to country grain elevators, country grain terminal elevators, grain terminal elevators and feed mill equipment, as these terms are defined in subrule 22.10(1). The requirements of this rule do not apply to equipment located at grain processing plants or grain storage elevators, as “grain processing” and “grain storage elevator” are defined in rule 567—20.2(455B). Compliance with the requirements of this rule does not alleviate any affected person’s duty to comply with any applicable state or federal regulations. In particular, the emission standards set forth in 567—Chapter 23, including the regulations for grain elevators contained in 40 CFR Part 60, Subpart DD (as adopted by reference in 567—paragraph 23.1(2)“ooo”), may apply. An owner or operator subject to this rule shall submit fees as required in 567—Chapter 30.

22.10(1) Definitions. For purposes of rule 567—22.10(455B), the following terms shall have the meanings indicated in this subrule.

“Country grain elevator” means any plant or installation at which grain is unloaded, handled, cleaned, dried, stored, or loaded and which meets the following criteria:

1. Receives more than 50 percent of its grain, as “grain” is defined in this subrule, from farmers in the immediate vicinity during harvest season;
2. Is not located at any wheat flour mill, wet corn mill, dry corn mill (human consumption), rice mill, or soybean oil extraction plant.

“Country grain terminal elevator” means any plant or installation at which grain is unloaded, handled, cleaned, dried, stored, or loaded and which meets the following criteria:

1. Receives 50 percent or less of its grain, as “grain” is defined in this subrule, from farmers in the immediate vicinity during harvest season;
2. Has a permanent storage capacity of less than or equal to 2.5 million U.S. bushels, as “permanent storage capacity” is defined in this subrule;
3. Is not located at any wheat flour mill, wet corn mill, dry corn mill (human consumption), rice mill, or soybean oil extraction plant.

“Feed mill equipment,” for purposes of rule 567—22.10(455B), means grain processing equipment that is used to make animal feed including, but not limited to, grinders, crackers, hammermills, and pellet coolers, and that is located at a country grain elevator, country grain terminal elevator or grain terminal elevator.

“*Grain*,” as set forth in Iowa Code section 203.1(9), means any grain for which the United States Department of Agriculture has established standards including, but not limited to, corn, wheat, oats, soybeans, rye, barley, grain sorghum, flaxseeds, sunflower seed, spelt (emmer), and field peas.

“*Grain processing*” shall have the same definition as “grain processing” set forth in rule 567—20.2(455B).

“*Grain storage elevator*” shall have the same definition as “grain storage elevator” set forth in rule 567—20.2(455B).

“*Grain terminal elevator*,” for purposes of rule 567—22.10(455B), means any plant or installation at which grain is unloaded, handled, cleaned, dried, stored, or loaded and which meets the following criteria:

1. Receives 50 percent or less of its grain, as “grain” is defined in this subrule, from farmers in the immediate vicinity during harvest season;
2. Has a permanent storage capacity of more than 88,100 m³ (2.5 million U.S. bushels), as “permanent storage capacity” is defined in this subrule;
3. Is not located at an animal food manufacturer, pet food manufacturer, cereal manufacturer, brewery, or livestock feedlot;
4. Is not located at any wheat flour mill, wet corn mill, dry corn mill (human consumption), rice mill, or soybean oil extraction plant.

“*Permanent storage capacity*” means grain storage capacity which is inside a building, bin, or silo.

22.10(2) Methods for determining potential to emit (PTE). The owner or operator of a country grain elevator, country grain terminal elevator, grain terminal elevator or feed mill equipment shall use the following methods for calculating the potential to emit (PTE) for particulate matter (PM) and for particulate matter with an aerodynamic diameter less than or equal to 10 microns (PM₁₀).

a. Country grain elevators. The owner or operator of a country grain elevator shall calculate the PTE for PM and PM₁₀ as specified in the definition of “potential to emit” in rule 567—20.2(455B), except that “maximum capacity” means the greatest amount of grain received at the country grain elevator during one calendar, 12-month period of the previous five calendar, 12-month periods, multiplied by an adjustment factor of 1.2. The owner or operator may make additional adjustments to the calculations for air pollution control of PM and PM₁₀ if the owner or operator submits the calculations to the department using the PTE calculation tool provided by the department, and only if the owner or operator fully implements the applicable air pollution control measures no later than March 31, 2009, or upon startup of the equipment, whichever event first occurs. Credit for the application of some best management practices, as specified in subrule 22.10(3) or in a permit issued by the department, may also be used to make additional adjustments in the PTE for PM and PM₁₀ if the owner or operator submits the calculations to the department using the PTE calculation tool provided by the department, and only if the owner or operator fully implements the applicable best management practices no later than March 31, 2009, or upon startup of the equipment, whichever event first occurs.

b. Country grain terminal elevators. The owner or operator of a country grain terminal elevator shall calculate the PTE for PM and PM₁₀ as specified in the definition of “potential to emit” in rule 567—20.2(455B).

c. Grain terminal elevators. For purposes of the permitting and other requirements specified in subrule 22.10(3), the owner or operator of a grain terminal elevator shall calculate the PTE for PM and PM₁₀ as specified in the definition of “potential to emit” in rule 567—20.2(455B). For purposes of determining whether the stationary source is subject to the prevention of significant deterioration (PSD) requirements set forth in 567—Chapter 33, or for determining whether the source is subject to the operating permit requirements set forth in rules 567—22.100(455B) through 567—22.300(455B), the owner or operator of a grain terminal elevator shall include fugitive emissions, as “fugitive emissions” is defined in 567—subrule 33.3(1) and in rule 567—22.100(455B), in the PTE calculation.

d. Feed mill equipment. The owner or operator of feed mill equipment, as “feed mill equipment” is defined in subrule 22.10(1), shall calculate the PTE for PM and PM₁₀ for the feed mill equipment as specified in the definition of “potential to emit” in rule 567—20.2(455B). For purposes of determining whether the stationary source is subject to the prevention of significant deterioration (PSD) requirements

set forth in 567—Chapter 33, or for determining whether the stationary source is subject to the operating permit requirements set forth in rules 567—22.100(455B) through 567—22.300(455B), the owner or operator of feed mill equipment shall sum the PTE of the feed mill equipment with the PTE of the country grain elevator, country grain terminal elevator or grain terminal elevator.

22.10(3) *Classification and requirements for permits, emissions controls, record keeping and reporting for Group 1, Group 2, Group 3 and Group 4 grain elevators.* The requirements for construction permits, operating permits, emissions controls, record keeping and reporting for a stationary source that is a country grain elevator, country grain terminal elevator or grain terminal elevator are set forth in this subrule.

a. Group 1 facilities. A country grain elevator, country grain terminal elevator or grain terminal elevator may qualify as a Group 1 facility if the PTE at the stationary source is less than 15 tons of PM₁₀ per year, as PTE is specified in subrule 22.10(2). For purposes of this paragraph, an “existing” Group 1 facility is one that commenced construction or reconstruction before February 6, 2008. A “new” Group 1 facility is one that commenced construction or reconstruction on or after February 6, 2008.

(1) Group 1 registration. The owner or operator of a Group 1 facility shall submit to the department a Group 1 registration, including PTE calculations, on forms provided by the department, certifying that the facility’s PTE is less than 15 tons of PM₁₀ per year. The owner or operator of an existing facility shall provide the Group 1 registration to the department on or before March 31, 2008. The owner or operator of a new facility shall provide the Group 1 registration to the department prior to initiating construction or reconstruction of a facility. The registration becomes effective upon the department’s receipt of the signed registration form and the PTE calculations.

1. If the owner or operator registers with the department as specified in subparagraph 22.10(3) “a”(1), the owner or operator is exempt from the requirement to obtain a construction permit as specified under subrule 22.1(1).

2. Upon department receipt of a Group 1 registration and PTE calculations, the owner or operator is allowed to add, remove and modify the emissions units or change throughput or operations at the facility without modifying the Group 1 registration, provided that the owner or operator calculates the PTE for PM₁₀ on forms provided by the department prior to making any additions to, removals of or modifications to equipment, and only if the facility continues to meet the emissions limits and operating limits (including restrictions on material throughput and hours of operation, if applicable, as specified in the PTE for PM₁₀ calculations) specified in the Group 1 registration.

3. If equipment at a Group 1 facility currently has an air construction permit issued by the department, that permit shall remain in full force and effect, and the permit shall not be invalidated by the subsequent submittal of a registration made pursuant to subparagraph 22.10(3) “a”(1).

(2) Best management practices (BMP). The owner or operator of a Group 1 facility shall implement best management practices (BMP) for controlling air pollution at the facility and for limiting fugitive dust at the facility from crossing the property line. The owner or operator shall implement BMP according to the department manual, Best Management Practices (BMP) for Grain Elevators (December 2007; revised July 15, 2014), as adopted by the commission on January 15, 2008, and July 15, 2014, and adopted by reference herein (available from the department, upon request, and on the department’s Internet website). No later than March 31, 2009, the owner or operator of an existing Group 1 facility shall fully implement applicable BMP, except that BMPs for grain vacuuming operations shall be fully implemented no later than September 10, 2014. Upon startup of equipment at the facility, the owner or operator of a new Group 1 facility shall fully implement applicable BMP.

(3) Record keeping. The owner or operator of a Group 1 facility shall retain a record of the previous five calendar years of total annual grain handled and shall calculate the facility’s potential PM₁₀ emissions annually by January 31 for the previous calendar year. These records shall be kept on site for a period of five years and shall be made available to the department upon request.

(4) Emissions increases. The owner or operator of a Group 1 facility shall calculate any emissions increases prior to making any additions to, removals of or modifications to equipment. If the owner or operator determines that PM₁₀ emissions at a Group 1 facility will increase to 15 tons per year or more,

the owner or operator shall comply with the requirements set forth for Group 2, Group 3 or Group 4 facilities, as applicable, prior to making any additions to, removals of or modifications to equipment.

(5) Changes to facility classification or permanent grain storage capacity. If the owner or operator of a Group 1 facility plans to change the facility's operations or increase the facility's permanent grain storage capacity to more than 2.5 million U.S. bushels, the owner or operator, prior to making any changes, shall reevaluate the facility's classification and the allowed method for calculating PTE to determine if any increases to the PTE for PM₁₀ will occur. If the proposed change will alter the facility's classification or will increase the facility's PTE for PM₁₀ such that the facility PTE increases to 15 tons per year or more, the owner or operator shall comply with the requirements set forth for Group 2, Group 3 or Group 4 facilities, as applicable, prior to making the change.

b. Group 2 facilities. A country grain elevator, country grain terminal elevator or grain terminal elevator may qualify as a Group 2 facility if the PTE at the stationary source is greater than or equal to 15 tons of PM₁₀ per year and is less than or equal to 50 tons of PM₁₀ per year, as PTE is specified in subrule 22.10(2). For purposes of this paragraph, an "existing" Group 2 facility is one that commenced construction, modification or reconstruction before February 6, 2008. A "new" Group 2 facility is one that commenced construction or reconstruction on or after February 6, 2008.

(1) Group 2 permit for grain elevators. The owner or operator of a Group 2 facility may, in lieu of obtaining air construction permits for each piece of emissions equipment at the facility, submit to the department a completed Group 2 permit application for grain elevators, including PTE calculations, on forms provided by the department. Alternatively, the owner or operator may obtain an air construction permit as specified under subrule 22.1(1). The owner or operator of an existing facility shall provide the appropriate completed Group 2 permit application for grain elevators or the appropriate construction permit applications to the department on or before March 31, 2008. The owner or operator of a new facility shall provide the appropriate, completed Group 2 permit application for grain elevators or the appropriate construction permit applications to the department prior to initiating construction or reconstruction of a facility.

1. Upon department issuance of a Group 2 permit to a facility, the owner or operator is allowed to add, remove and modify the emissions units at the facility, or change throughput or operations, without modifying the Group 2 permit, provided that the owner or operator calculates the PTE for PM₁₀ prior to making any additions to, removals of or modifications to equipment, and only if the facility continues to meet the emissions limits and operating limits (including restrictions on material throughput and hours of operation, if applicable, as specified in the PTE for PM₁₀ calculations) specified in the Group 2 permit.

2. If a Group 2 facility currently has an air construction permit issued by the department, that permit shall remain in full force and effect, and the permit shall not be invalidated by the subsequent submittal of a Group 2 permit application for grain elevators made pursuant to this rule. However, the owner or operator of a Group 2 facility may request that the department incorporate any equipment with a previously issued construction permit into the Group 2 permit for grain elevators. The department will grant such requests on a case-by-case basis. If the department grants the request to incorporate previously permitted equipment into the Group 2 permit for grain elevators, the owner or operator of the Group 2 facility is responsible for requesting that the department rescind any previously issued construction permits.

(2) Best management practices (BMP). The owner or operator shall implement BMP, as specified in the Group 2 permit, for controlling air pollution at the source and for limiting fugitive dust at the source from crossing the property line. If the department revises the BMP requirements for Group 2 facilities after a facility is issued a Group 2 permit, the owner or operator of the Group 2 facility may request that the department modify the facility's Group 2 permit to incorporate the revised BMP requirements. The department will issue permit modifications to incorporate BMP revisions on a case-by-case basis. No later than March 31, 2009, the owner or operator of an existing Group 2 facility shall fully implement BMP, as specified in the Group 2 permit. Upon startup of equipment at the facility, the owner or operator of a new Group 2 facility shall fully implement BMP, as specified in the Group 2 permit.

(3) Record keeping. The owner or operator of a Group 2 facility shall retain all records as specified in the Group 2 permit.

(4) Emissions inventory. The owner or operator of a Group 2 facility shall submit an emissions inventory for the facility for all regulated air pollutants as specified under 567—subrule 21.1(3).

(5) Emissions increases. The owner or operator of a Group 2 facility shall calculate any emissions increases prior to making any additions to, removals of or modifications to equipment. If the owner or operator determines that potential PM₁₀ emissions at a Group 2 facility will increase to more than 50 tons per year, the owner or operator shall comply with the requirements set forth for Group 3 or Group 4 facilities, as applicable, prior to making any additions to, removals of or modifications to equipment.

(6) Changes to facility classification or permanent grain storage capacity. If the owner or operator of a Group 2 facility plans to change the facility's operations or increase the facility's permanent grain storage capacity to more than 2.5 million U.S. bushels, the owner or operator, prior to making any changes, shall reevaluate the facility's classification and the allowed method for calculating PTE to determine if any increases to the PTE for PM₁₀ will occur. If the proposed change will increase the facility's PTE for PM₁₀ such that the facility PTE increases to more than 50 tons per year, the owner or operator shall comply with the requirements set forth for Group 3 or Group 4 facilities, as applicable, prior to making the change.

c. Group 3 facilities. A country grain elevator, country grain terminal elevator or grain terminal elevator may qualify as a Group 3 facility if the PTE for PM₁₀ at the stationary source is greater than 50 tons per year, but is less than 100 tons of PM₁₀ per year, as PTE is specified in subrule 22.10(2). For purposes of this paragraph, an "existing" Group 3 facility is one that commenced construction, modification or reconstruction before February 6, 2008. A "new" Group 3 facility is one that commenced construction or reconstruction on or after February 6, 2008.

(1) Air construction permit. The owner or operator of a Group 3 facility shall obtain the required construction permits as specified under subrule 22.1(1). The owner or operator of an existing facility shall provide the construction permit applications, as specified in subrule 22.1(3), to the department on or before March 31, 2008. The owner or operator of a new facility shall obtain the required permits, as specified in subrule 22.1(1), from the department prior to initiating construction or reconstruction of a facility.

(2) Permit conditions. Construction permit conditions for a Group 3 facility shall include, but are not limited to, the following:

1. The owner or operator shall implement BMP, as specified in the permit, for controlling air pollution at the source and for limiting fugitive dust at the source from crossing the property line. If the department revises the BMP requirements for Group 3 facilities after a facility is issued a permit, the owner or operator of the Group 3 facility may request that the department modify the facility's permit to incorporate the revised BMP requirements. The department will issue permit modifications to incorporate BMP revisions on a case-by-case basis.

2. The owner or operator shall retain all records as specified in the permit.

(3) Emissions inventory. The owner or operator shall submit an emissions inventory for the facility for all regulated air pollutants as specified under 567—subrule 21.1(3).

(4) Changes to facility classification or permanent grain storage capacity. If the owner or operator of a Group 3 facility plans to change its operations or increase the facility's permanent grain storage capacity to more than 2.5 million U.S. bushels, the owner or operator, prior to making any changes, shall reevaluate the facility's classification and the allowed method for calculating PTE to determine if any increases to the PTE for PM₁₀ will occur. If the proposed change will alter the facility's classification or will increase the facility's PTE for PM₁₀ such that the facility PTE increases to greater than or equal to 100 tons per year, the owner or operator shall comply with the requirements set forth for Group 4 facilities, as applicable, prior to making the change.

(5) PSD applicability. If the PTE for PM or PM₁₀ at the Group 3 facility is greater than or equal to 250 tons per year, the owner or operator shall comply with requirements specified in 567—Chapter 33, as applicable. The owner or operator of a Group 3 facility that is a grain terminal elevator shall include fugitive emissions, as "fugitive emissions" is defined in 567—subrule 33.3(1), in the PTE calculation for determining PSD applicability.

(6) Record keeping. The owner or operator shall keep the records of annual grain handled at the facility and annual PTE for PM and PM₁₀ emissions on site for a period of five years, and the records shall be made available to the department upon request.

d. Group 4 facilities. A facility qualifies as a Group 4 facility if the facility is a stationary source with a PTE equal to or greater than 100 tons of PM₁₀ per year, as PTE is specified in subrule 22.10(2). For purposes of this paragraph, an “existing” Group 4 facility is one that commenced construction, modification or reconstruction before February 6, 2008. A “new” Group 4 facility is one that commenced construction or reconstruction on or after February 6, 2008.

(1) Air construction permit. The owner or operator of a Group 4 facility shall obtain the required construction permits as specified under subrule 22.1(1). The owner or operator of an existing facility shall provide the construction permit applications, as specified by subrule 22.1(3), to the department on or before March 31, 2008. The owner or operator of a new facility shall obtain the required permits, as specified by subrule 22.1(1), from the department prior to initiating construction or reconstruction of a facility.

(2) Permit conditions. Construction permit conditions for a Group 4 facility shall include, but are not limited to, the following:

1. The owner or operator shall implement BMP, as specified in the permit, for controlling air pollution at the facility and for limiting fugitive dust at the facility from crossing the property line. If the department revises the BMP requirements for Group 4 facilities after a facility is issued a permit, the owner or operator of the Group 4 facility may request that the department modify the facility’s permit to incorporate the revised BMP requirements. The department will issue permit modifications to incorporate BMP revisions on a case-by-case basis.

2. The owner or operator shall retain all records as specified in the permit.

(3) PSD applicability. If the PTE for PM or PM₁₀ at the facility is equal to or greater than 250 tons per year, the owner or operator shall comply with requirements specified in 567—Chapter 33, as applicable. The owner or operator of a Group 4 facility that is a grain terminal elevator shall include fugitive emissions, as “fugitive emissions” is defined in 567—subrule 33.3(1), in the PTE calculation for determining PSD applicability.

(4) Record keeping. The owner or operator shall keep the records of annual grain handled at the facility and annual PTE for PM and PM₁₀ emissions on site for a period of five years, and the records shall be made available to the department upon request.

(5) Operating permits. The owner or operator of a Group 4 facility shall apply for an operating permit for the facility if the facility’s annual PTE for PM₁₀ is equal to or greater than 100 tons per year as specified in rules 567—22.100(455B) through 567—22.300(455B). The owner or operator of a Group 4 facility that is a grain terminal elevator shall include fugitive emissions in the calculations to determine if the PTE for PM₁₀ is greater than or equal to 100 tons per year. The owner or operator also shall submit annual emissions inventories and fees, as specified in rule 567—22.106(455B).

22.10(4) Feed mill equipment. This subrule sets forth the requirements for construction permits, operating permits, and emissions inventories for an owner or operator of feed mill equipment as “feed mill equipment” is defined in subrule 22.10(1). For purposes of this subrule, the owner or operator of “existing” feed mill equipment shall have commenced construction or reconstruction of the feed mill equipment before February 6, 2008. The owner or operator of “new” feed mill equipment shall have commenced construction or reconstruction of the feed mill equipment on or after February 6, 2008.

a. Air construction permit. The owner or operator of feed mill equipment shall obtain an air construction permit as specified under subrule 22.1(1) for each piece of feed mill equipment that emits a regulated air pollutant. The owner or operator of “existing” feed mill equipment shall provide the appropriate permit applications to the department on or before March 31, 2008. The owner or operator of “new” feed mill equipment shall provide the appropriate permit applications to the department prior to initiating construction or reconstruction of feed mill equipment.

b. Emissions inventory. The owner or operator shall submit an emissions inventory for the feed mill equipment for all regulated air pollutants as specified under 567—subrule 21.1(3).

c. Operating permits. The owner or operator shall sum the PTE of the feed mill equipment with the PTE of the equipment at the country grain elevator, country grain terminal elevator or grain terminal elevator, as PTE is specified in subrule 22.10(2), to determine if operating permit requirements specified in rules 567—22.100(455B) through 567—22.300(455B) apply to the stationary source. If the operating permit requirements apply, then the owner or operator shall apply for an operating permit as specified in rules 567—22.100(455B) through 567—22.300(455B). The owner or operator also shall begin submitting annual emissions inventories and fees, as specified under rule 567—22.106(455B).

d. PSD applicability. For purposes of determining whether the stationary source is subject to the prevention of significant deterioration (PSD) requirements set forth in 567—Chapter 33, the owner or operator shall sum the PTE of the feed mill equipment with the PTE of the equipment at the country grain elevator, country grain terminal elevator or grain terminal elevator. If the PTE for PM or PM₁₀ for the stationary source is equal to or greater than 250 tons per year, the owner or operator shall comply with requirements for PSD specified in 567—Chapter 33, as applicable.

[ARC 1561C, IAB 8/6/14, effective 9/10/14; ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—22.11 to 22.99 Reserved.

567—22.100(455B) Definitions for Title V operating permits. For purposes of rules 567—22.100(455B) to 567—22.116(455B), the following terms shall have the meaning indicated in this rule:

“*Act*” means the Clean Air Act, 42 U.S.C. Sections 7401, et seq.

“*Actual emissions*” means the actual rate of emissions of a pollutant from an emissions unit, as determined in accordance with the following:

1. In general, actual emissions as of a particular date shall equal the average rate, in tons per year, at which the unit actually emitted the pollutant during a two-year period which immediately precedes that date and which is representative of normal source operations. The director may allow the use of a different time period upon a demonstration that it is more representative of normal source operations. Actual emissions shall be calculated using the unit’s actual operating hours, production rates, and types of materials processed, stored or combusted during the selected time period. Actual emissions for acid rain affected sources are calculated using a one-year period.

2. Lacking specific information to the contrary, the director may presume that source-specific allowable emissions for the unit are equivalent to the actual emissions of the unit.

3. For any emissions unit which has not begun normal operations on a particular date, actual emissions shall equal the potential to emit of the unit on that date.

4. For purposes of calculating early reductions of hazardous air pollutants, actual emissions shall not include excess emissions resulting from a malfunction or from startups and shutdowns associated with a malfunction.

Actual emissions for purposes of determining fees shall be the actual emissions calculated over a period of one year.

“*Administrator*” means the administrator for the United States Environmental Protection Agency (EPA) or designee.

“*Affected facility*” means, with reference to a stationary source, any apparatus which emits or may emit any regulated air pollutant or contaminant.

“*Affected source*” means a source that includes one or more affected units subject to any emissions reduction requirement or limitation under Title IV of the Act.

“*Affected state*” means any state which is contiguous to the permitting state and whose air quality may be affected through the modification, renewal or issuance of a Title V permit; or which is within 50 miles of the permitted source.

“*Affected unit*” means a unit that is subject to any acid rain emissions reduction requirement or acid rain emissions limitation under Title IV of the Act.

“*Allowable emissions*” means the emission rate of a stationary source calculated using both the maximum rated capacity of the source, unless the source is subject to federally enforceable limits which restrict the operating rate or hours of operation, and the most stringent of the following:

1. The applicable new source performance standards or national emissions standards for hazardous air pollutants, contained in 567—subrules 23.1(2) and 23.1(3);
2. The applicable existing source emission standard contained in 567—Chapter 23; or
3. The emissions rate specified in the air construction permit for the source.

“*Allowance*” means an authorization by the administrator under Title IV of the Act or rules promulgated thereunder to emit during or after a specified calendar year up to one ton of sulfur dioxide.

“*Applicable requirement*” includes the following:

1. Any standard or other requirement provided for in the applicable implementation plan approved or promulgated by EPA through rule making under Title I of the Act that implements the relevant requirements of the Act, including any revisions to that plan promulgated in 40 CFR 52;
2. Any term or condition of any preconstruction permits issued pursuant to regulations approved or promulgated through rule making under Title I, including Parts C and D, of the Act;
3. Any standard or other requirement under Section 111 of the Act (subrule 23.1(2)), including Section 111(d);
4. Any standard or other requirement under Section 112 of the Act, including any requirement concerning accident prevention under Section 112(r)(7) of the Act;
5. Any standard or other requirement of the acid rain program under Title IV of the Act or the regulations promulgated thereunder;
6. Any requirements established pursuant to Section 504(b) or Section 114(a)(3) of the Act;
7. Any standard or other requirement governing solid waste incineration, under Section 129 of the Act;
8. Any standard or other requirement for consumer and commercial products, under Section 183(e) of the Act;
9. Any standard or other requirement for tank vessels under Section 183(f) of the Act;
10. Any standard or other requirement of the program to control air pollution from outer continental shelf sources, under Section 328 of the Act;
11. Any standard or other requirement of the regulations promulgated to protect stratospheric ozone under Title VI of the Act, unless the administrator has determined that such requirements need not be contained in a Title V permit; and
12. Any national ambient air quality standard or increment or visibility requirement under Part C of Title I of the Act, but only as it would apply to temporary sources permitted pursuant to Section 504(e) of the Act.

“*Area source*” means any stationary source of hazardous air pollutants that is not a major source as defined in rule 567—22.100(455B).

“*CFR*” means the Code of Federal Regulations, with standard references in this chapter by Title and Part, so that “40 CFR 51” means “Title 40 of the Code of Federal Regulations, Part 51.”

“*Consumer Price Index*” means for any calendar year the average of the Consumer Price Index for all urban consumers published by the United States Department of Labor, as of the close of the 12-month period ending on August 31 of each calendar year.

“*Country grain elevator*” shall have the same definition as “country grain elevator” set forth in subrule 22.10(1).

“*Designated representative*” means a responsible natural person authorized by the owner(s) or operator(s) of an affected source and of all affected units at the source, as evidenced by a certificate of representation submitted in accordance with Subpart B of 40 CFR Part 72 as amended through April 28, 2006, to represent and legally bind each owner and operator, as a matter of federal law, in matters pertaining to the acid rain program. Whenever the term “responsible official” is used in Chapter 22, it shall be deemed to refer to the designated representative with regard to all matters under the acid rain program.

“*Draft Title V permit*” means the version of a Title V permit for which the department offers public participation or affected state review.

“*Electronic format,*” “*electronic submittal,*” and “*electronic submittal format*” mean a software, Internet-based, or other electronic means specified by the department for submitting information or fees to the department related to, but not limited to, applications, certifications, determination requests, emissions inventories, forms, notifications, payments, permit applications and registrations. References to these information submittal methods in rules 567—22.100(455B) through 567—22.116(455B) may, as specified by the department, include electronic submittal.

“*Emergency generator*” means any generator of which the sole function is to provide emergency backup power during an interruption of electrical power from the electric utility. An emergency generator does not include:

1. Peaking units at electric utilities;
2. Generators at industrial facilities that typically operate at low rates, but are not confined to emergency purposes; or
3. Any standby generators that are used during time periods when power is available from the electric utility.

An emergency is an unforeseeable condition that is beyond the control of the owner or operator.

“*Emissions allowable under the permit*” means a federally enforceable permit term or condition determined at issuance to be required by an applicable requirement that establishes an emissions limit (including a work practice standard) or a federally enforceable emissions cap that the source has assumed to avoid an applicable requirement to which the source would otherwise be subject.

“*Emissions unit*” means any part or activity of a stationary source that emits or has the potential to emit any regulated air pollutant or any pollutant listed under Section 112(b) of the Act. This term is not meant to alter or affect the definition of the term “unit” for purposes of Title IV of the Act or any related regulations.

“*EPA conditional method*” means any method of sampling and analyzing for air pollutants that has been validated by the administrator but that has not been published as an EPA reference method.

“*EPA reference method*” means the following methods used for performance tests and continuous monitoring systems:

1. Performance test (stack test). A stack test shall be conducted according to EPA reference methods specified in 40 CFR 51, Appendix M (as amended through November 14, 2018); 40 CFR 60, Appendix A (as amended through November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through November 14, 2018).
2. Continuous monitoring systems. Minimum performance specifications and quality assurance procedures for performance evaluations of continuous monitoring systems are as specified in 40 CFR 60, Appendix B (as amended through November 14, 2018); 40 CFR 60, Appendix F (as amended through November 14, 2018); 40 CFR 75, Appendix A (as amended through August 30, 2016); 40 CFR 75, Appendix B (as amended through August 30, 2016); and 40 CFR 75, Appendix F (as amended through August 30, 2016).

“*Equipment leaks*” means leaks from pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, agitators, accumulator vessels, and instrumentation systems.

“*Existing hazardous air pollutant source*” means any source as defined in 40 CFR 61 as adopted by reference in 567—subrule 23.1(3) and 40 CFR 63.72 as adopted by reference in 567—subrule 23.1(4) with respect to Section 112(i)(5) of the Act, the construction or reconstruction of which commenced prior to proposal of an applicable Section 112(d) standard.

“*Facility*” means, with reference to a stationary source, any apparatus which emits or may emit any air pollutant or contaminant.

“*Federal implementation plan*” means a plan promulgated by the administrator to fill all or a portion of a gap or otherwise correct all or a portion of an inadequacy in a state implementation plan, and which includes enforceable emission limitations or other control measures, means or techniques, and provides for attainment of the relevant national ambient air quality standard.

“*Federally enforceable*” means all limitations and conditions which are enforceable by the administrator including, but not limited to, the requirements of the new source performance standards and national emission standards for hazardous air pollutants contained in 567—subrules 23.1(2) and 23.1(3); the requirements of such other state rules or orders approved by the administrator for inclusion in the SIP; and any construction, Title V or other federally approved operating permit conditions.

“*Final Title V permit*” means the version of a Title V permit issued by the department that has completed all required review procedures.

“*Fugitive emissions*” are those emissions which could not reasonably pass through a stack, chimney, vent or other functionally equivalent opening.

“*Hazardous air pollutant*” means any of the following air pollutants listed in Section 112 of the Act:

cas #	chemical name
75343	1,1-Dichloroethane
57147	1,1-Dimethyl hydrazine
71556	1,1,1-Trichloroethane
79005	1,1,2-Trichloroethane
79345	1,1,2,2-Tetrachloroethane
106887	1,2-Butylene oxide
96128	1,2-Dibromo-3-chloropropane
106934	1,2-Dibromoethane
107062	1,2-Dichloroethane
78875	1,2-Dichloropropane
122667	1,2-Diphenylhydrazine
120821	1,2,4-Trichlorobenzene
106990	1,3-Butadiene
542756	1,3-Dichloropropylene
106467	1,4-Dichlorobenzene
123911	1,4-Dioxane
53963	2-Acetylaminofluorene
532274	2-Chloroacetophenone
79469	2-Nitropropane
540841	2,2,4-Trimethylpentane
1746016	2,3,7,8-Tetrachlorodibenzo-p-dioxin (TC-DD)
94757	2,4-D salts and esters
95807	2,4-Diaminotoluene
51285	2,4-Dinitrophenol
121142	2,4-Dinitrotoluene
95954	2,4,5-Trichlorophenol
88062	2,4,6-Trichlorophenol
91941	3,3'-Dichlorobenzidine
119904	3,3'-Dimethoxybenzidine
119937	3,3'-Dimethylbenzidine
92671	4-Aminobiphenyl
60117	4-Dimethylaminoazobenzene

cas #	chemical name
92933	4-Nitrobiphenyl
100027	4-Nitrophenol
101144	4,4'-Methylenebis(2-chloroaniline)
101779	4,4'-methylenedianiline
534521	4,6-Dinitro-o-cresol, and salts
75070	Acetaldehyde
60355	Acetamide
75058	Acetonitrile
98862	Acetophenone
107028	Acrolein
79061	Acrylamide
79107	Acrylic acid
107131	Acrylonitrile
107051	Allyl chloride
62533	Aniline
0	Antimony Compounds
0	Arsenic Compounds (inorganic including arsine)
1332214	Asbestos (friable)
71432	Benzene
92875	Benzidine
98077	Benzoic trichloride
100447	Benzyl chloride
0	Beryllium Compounds
57578	Beta-Propiolactone
92524	Biphenyl
111444	Bis(2-chloroethyl) ether
542881	Bis(chloromethyl) ether
75252	Bromoform
74839	Bromomethane
0	Cadmium Compounds
156627	Calcium cyanamide
133062	Captan
63252	Carbaryl
75150	Carbon disulfide
56235	Carbon tetrachloride
463581	Carbonyl sulfide
120809	Catechol
133904	Chloramben
57749	Chlordane
7782505	Chlorine
79118	Chloroacetic acid

cas #	chemical name
108907	Chlorobenzene
510156	Chlorobenzilate
75003	Chloroethane
67663	Chloroform
74873	Chloromethane
107302	Chloromethyl methyl ether
126998	Chloroprene
0	Chromium Compounds
0	Cobalt Compounds
0	Coke Oven Emissions
1319773	Cresol/Cresylic acid (isomers & mixture)
98828	Cumene
0	Cyanide Compounds ¹
72559	DDE
117817	Di(2-ethylhexyl) phthalate
334883	Diazomethane
132649	Dibenzofuran
84742	Dibutyl phthalate
75092	Dichloromethane
62737	Dichlorvos
111422	Diethanolamine
64675	Diethyl sulfate
68122	Dimethyl formamide
131113	Dimethyl phthalate
77781	Dimethyl sulfate
79447	Dimethylcarbamyl chloride
106898	Epichlorohydrin
140885	Ethyl acrylate
100414	Ethylbenzene
107211	Ethylene glycol
75218	Ethylene oxide
96457	Ethylene thiourea
151564	Ethyleneimine
0	Fine Mineral Fibers ³
50000	Formaldehyde
0	Glycol Ethers ² , except cas #111-76-2, ethylene glycol mono-butyl ether, also known as EGBE or 2-Butoxyethanol
76448	Heptachlor
87683	Hexachloro-1,3-butadiene
118741	Hexachlorobenzene
77474	Hexachlorocyclopentadiene

cas #	chemical name
67721	Hexachloroethane
822060	Hexamethylene-1,6-diisocyanate
680319	Hexamethylphosphoramide
110543	Hexane
302012	Hydrazine
7647010	Hydrochloric acid
7664393	Hydrogen fluoride
123319	Hydroquinone
78591	Isophorone
0	Lead Compounds
58899	Lindane (all isomers)
108394	m-Cresol
108383	m-Xylene
108316	Maleic anhydride
0	Manganese Compounds
0	Mercury Compounds
67561	Methanol
72435	Methoxychlor
60344	Methyl hydrazine
74884	Methyl iodide
108101	Methyl isobutyl ketone
624839	Methyl isocyanate
80626	Methyl methacrylate
1634044	Methyl tertbutyl ether
101688	Methylene bis(phenylisocyanate)
684935	N-Nitroso-N-methylurea
62759	N-Nitrosodimethylamine
59892	N-Nitrosomorpholine
91203	Naphthalene
0	Nickel Compounds
98953	Nitrobenzene
121697	N,N-Dimethylaniline
90040	o-Anisidine
95487	o-Cresol
95534	o-Toluidine
95476	o-Xylene
106445	p-Cresol
106503	p-Phenylenediamine
106423	p-Xylene
56382	Parathion
87865	Pentachlorophenol

cas #	chemical name
108952	Phenol
75445	Phosgene
7803512	Phosphine
7723140	Phosphorus (yellow or white)
85449	Phthalic anhydride
1336363	Polychlorinated biphenyls
0	Polycyclic Organic Matter ⁴
1120714	Propane sultone
123386	Propionaldehyde
114261	Propoxur
75569	Propylene oxide
75558	Propyleneimine
91225	Quinoline
106514	Quinone
82688	Quintozene
0	Radionuclides (including Radon) ⁵
0	Selenium Compounds
100425	Styrene
96093	Styrene oxide
127184	Tetrachloroethylene
7550450	Titanium tetrachloride
108883	Toluene
584849	Toluene-2,4-diisocyanate
8001352	Toxaphene
79016	Trichloroethylene
121448	Triethylamine
1582098	Trifluralin
51796	Urethane
108054	Vinyl acetate
593602	Vinyl bromide
75014	Vinyl chloride
75354	Vinylidene chloride
1330207	Xylene (mixed isomers)

NOTE: For all listings above which contain the word “compounds” and for glycol ethers, the following applies: Unless otherwise specified, these listings are defined as including any unique chemical substance that contains the named chemical (i.e., antimony, arsenic, etc.) as part of that chemical’s infrastructure.

¹X’CN where X=H’ or any other group where a formal dissociation may occur. For example KCN or Ca(CN)₂

²Includes mono- and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol R(OCH₂CH₂)_n-OR’ where n=1,2, or 3; R=alkyl or aryl groups; R’=R,H, or groups which, when removed, yield glycol ethers with the structure R(OCH₂CH)_n-OH. Polymers are excluded from the glycol category.

³Includes mineral fiber emissions from facilities manufacturing or processing glass, rock, or slag fibers (or other mineral derived fibers) of average diameter 1 micrometer or less.

⁴Includes organic compounds with more than one benzene ring, and which have a boiling point greater than or equal to 100 degrees C.

⁵A type of atom which spontaneously undergoes radioactive decay.

“*High-risk pollutant*” means one of the following hazardous air pollutants listed in Table 1 in 40 CFR 63.74 as adopted by reference in 567—subrule 23.1(4).

cas #	chemical name	weighting factor
53963	2-Acetylaminofluorene	100
107028	Acrolein	100
79061	Acrylamide	10
107131	Acrylonitrile	10
0	Arsenic compounds	100
1332214	Asbestos	100
71432	Benzene	10
92875	Benzidine	1000
0	Beryllium compounds	10
542881	Bis(chloromethyl) ether	1000
106990	1,3-Butadiene	10
0	Cadmium compounds	10
57749	Chlordane	100
532274	2-Chloroacetophenone	100
0	Chromium compounds	100
107302	Chloromethyl methyl ether	10
0	Coke oven emissions	10
334883	Diazomethane	10
132649	Dibenzofuran	10
96128	1,2-Dibromo-3-chloropropane	10
111444	Dichloroethyl ether(Bis(2-chloroethyl) ether)	10
79447	Dimethylcarbonyl chloride	100
122667	1,2-Diphenylhydrazine	10
106934	Ethylene dibromide	10
151564	Ethylenimine (Aziridine)	100
75218	Ethylene oxide	10
76448	Heptachlor	100
118741	Hexachlorobenzene	100
77474	Hexachlorocyclopentadiene	100
302012	Hydrazine	100
0	Manganese compounds	10
0	Mercury compounds	100
60344	Methyl hydrazine	10
624839	Methyl isocyanate	10
0	Nickel compounds	10

cas #	chemical name	weighting factor
62759	N-Nitrosodimethylamine	100
684935	N-Nitroso-N-methylurea	1000
56382	Parathion	10
75445	Phosgene	10
7803512	Phosphine	10
7723140	Phosphorus	10
75558	1,2-Propylenimine	100
1746016	2,3,7,8-Tetrachlorodibenzo-p-dioxin	100,000
8001352	Toxaphene (chlorinated camphene)	100
75014	Vinyl chloride	10

“*Major source*” means any stationary source (or any group of stationary sources located on one or more contiguous or adjacent properties and under common control of the same person or of persons under common control) belonging to a single major industrial grouping that is any of the following:

1. A major stationary source of air pollutants, as defined in Section 302 of the Act, that directly emits or has the potential to emit 100 tons per year (tpy) or more of any air pollutant subject to regulation (including any major source of fugitive emissions of any such pollutant). The fugitive emissions of a stationary source shall not be considered in determining whether it is a major stationary source for the purposes of Section 302(j) of the Act, unless the source belongs to one of the stationary source categories listed in this chapter.

2. A major source of hazardous air pollutants according to Section 112 of the Act as follows:

For pollutants other than radionuclides, any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, in the aggregate, 10 tpy or more of any hazardous air pollutant which has been listed pursuant to Section 112(b) of the Act and these rules or 25 tpy or more of any combination of such hazardous air pollutants. Notwithstanding the previous sentence, emissions from any oil or gas exploration or production well (with its associated equipment) and emission from any pipeline compressor or pump station shall not be aggregated with emissions from other similar units, whether or not such units are in a contiguous area or under common control, to determine whether such units or stations are major sources.

For Title V purposes, all fugitive emissions of hazardous air pollutants are to be considered in determining whether a stationary source is a major source.

For radionuclides, “major source” shall have the meaning specified by the administrator by rule.

3. A major stationary source as defined in Part D of Title I of the Act, including:

For ozone nonattainment areas, sources with the potential to emit 100 tpy or more of volatile organic compounds or oxides of nitrogen in areas classified or treated as classified as “marginal” or “moderate,” 50 tpy or more in areas classified or treated as classified as “serious,” 25 tpy or more in areas classified or treated as classified as “severe” and 10 tpy or more in areas classified or treated as classified as “extreme”; except that the references in this paragraph to 100, 50, 25, and 10 tpy of nitrogen oxides shall not apply with respect to any source for which the administrator has made a finding, under Section 182(f)(1) or (2) of the Act, that requirements under Section 182(f) of the Act do not apply;

For ozone transport regions established pursuant to Section 184 of the Act, sources with potential to emit 50 tpy or more of volatile organic compounds;

For carbon monoxide nonattainment areas (1) that are classified or treated as classified as “serious” and (2) in which stationary sources contribute significantly to carbon monoxide levels, and sources with the potential to emit 50 tpy or more of carbon monoxide;

For particulate matter (PM₁₀), nonattainment areas classified or treated as classified as “serious,” sources with the potential to emit 70 tpy or more of PM₁₀.

For the purposes of defining “major source,” a stationary source or group of stationary sources shall be considered part of a single industrial grouping if all of the pollutant emitting activities at such source or group of sources on contiguous or adjacent properties belong to the same major group (i.e., all have the same two-digit code) as described in the Standard Industrial Classification Manual, 1987.

“*Manually operated equipment*” means a machine or tool that is handheld, such as a handheld circular saw or compressed air chisel; a machine or tool for which the work piece is held or manipulated by hand, such as a bench grinder; a machine or tool for which the tool or bit is manipulated by hand, such as a lathe or drill press; and any dust collection system which is part of such machine or tool; but not including any machine or tool for which the extent of manual operation is to control power to the machine or tool and not including any central dust collection system serving more than one machine or tool.

“*Maximum achievable control technology (MACT)*” means the following regarding regulated hazardous air pollutant sources:

1. For existing sources, the emissions limitation reflecting the maximum degree of reduction in emissions that the administrator or the department, taking into consideration the cost of achieving such emission reduction, and any nonair quality health and environmental impacts and energy requirements, determines is achievable by sources in the category of stationary sources, that shall not be less stringent than the MACT floor.

2. For new sources, the emission limitation which is not less stringent than the emission limitation achieved in practice by the best-controlled similar source, and which reflects the maximum degree of reduction in emissions that the administrator or the department, taking into consideration the cost of achieving such emission reduction, and any nonair quality health and environmental impacts and energy requirements, determines is achievable by sources in the Title IV affected source category.

“*Maximum achievable control technology (MACT) floor*” means the following:

1. For existing sources, the average emission limitation achieved by the best 12 percent of the existing sources in the United States (for which the administrator or the department has or could reasonably obtain emission information), excluding those sources that have, within 18 months before the emission standard is proposed or within 30 months before such standard is promulgated, whichever is later, first achieved a level of emission rate or emission reduction which complies, or would comply if the source is not subject to such standard, with the lowest achievable emission rate applicable to the source category and prevailing at the time, for categories and subcategories of stationary sources with 30 or more sources in the category or subcategory, or the average emission limitation achieved by the best performing 5 sources in the United States (for which the administrator or the department has or could reasonably obtain emissions information) for a category or subcategory or stationary source with fewer than 30 sources in the category or subcategory.

2. For new sources, the emission limitation achieved in practice by the best-controlled similar source.

“*New Title IV affected source or unit*” means a unit that commences commercial operation on or after November 15, 1990, including any such unit that serves a generator with a nameplate capacity of 25 MWe or less or that is a simple combustion turbine.

“*Nonattainment area*” means an area so designated by the administrator, acting pursuant to Section 107 of the Act.

“*Permit modification*” means a revision to a Title V operating permit that cannot be accomplished under the provisions for administrative permit amendments found at rule 567—22.111(455B). A permit modification for purposes of the acid rain portion of the permit shall be governed by the regulations pertaining to acid rain found at rules 567—22.120(455B) to 567—22.147(455B). This definition of “permit modification” shall be used solely for purposes of this chapter governing Title V operating permits.

“*Permit revision*” means any permit modification or administrative permit amendment.

“*Permitting authority*” means the Iowa department of natural resources or the director thereof.

“*Potential to emit*” means the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a

source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation is enforceable by the administrator. This term does not alter or affect the use of this term for any other purposes under the Act, or the term “capacity factor” as used in Title IV of the Act or the regulations relating to acid rain.

For the purpose of determining potential to emit for country grain elevators, the provisions set forth in subrule 22.10(2) shall apply.

For purposes of calculating potential to emit for emergency generators, “maximum capacity” means one of the following:

1. 500 hours of operation annually, if the generator has actually been operated less than 500 hours per year for the past five years;
2. 8,760 hours of operation annually, if the generator has actually been operated more than 500 hours in one of the past five years; or
3. The number of hours specified in a state or federally enforceable limit.

“*Proposed Title V permit*” means the version of a permit that the permitting authority proposes to issue and forwards to the administrator for review in compliance with 22.107(7)“a.”

“*Regulated air contaminant*” shall mean the same thing as “regulated air pollutant.”

“*Regulated air pollutant*” means the following:

1. Nitrogen oxides or any volatile organic compounds;
2. Any pollutant for which a national ambient air quality standard has been promulgated;
3. Any pollutant that is subject to any standard promulgated under Section 111 of the Act;
4. Any Class I or II substance subject to a standard promulgated under or established by Title VI of the Act; or

5. Any pollutant subject to a standard promulgated under Section 112 or other requirements established under Section 112 of the Act, including Sections 112(g), (j), and (r) of the Act, including the following:

- Any pollutant subject to requirements under Section 112(j) of the Act. If the administrator fails to promulgate a standard by the date established pursuant to Section 112(e) of the Act, any pollutant for which a subject source would be major shall be considered to be regulated on the date 18 months after the applicable date established pursuant to Section 112(e) of the Act; and

- Any pollutant for which the requirements of Section 112(g)(2) of the Act have been met, but only with respect to the individual source subject to the Section 112(g)(2) requirement.

6. With respect to Title V, particulate matter, except for PM10, is not considered a regulated air pollutant for the purpose of determining whether a source is considered to be a major source.

“*Regulated air pollutant or contaminant (for fee calculation)*,” which is used only for purposes of 567—Chapter 30, means any “regulated air pollutant or contaminant” except the following:

1. Carbon monoxide;
2. Particulate matter, excluding PM10;
3. Any pollutant that is a regulated air pollutant solely because it is a Class I or II substance subject to a standard promulgated under or established by Title VI of the Act;
4. Any pollutant that is a regulated pollutant solely because it is subject to a standard or regulation under Section 112(r) of the Act;
5. Greenhouse gas, as defined in rule 567—20.2(455B).

“*Renewal*” means the process by which a permit is reissued at the end of its term.

“*Responsible official*” means one of the following:

1. For a corporation: a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:

- The facilities employ more than 250 persons or have gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars); or

- The delegation of authority to such representative is approved in advance by the permitting authority.

2. For a partnership or sole proprietorship: a general partner or the proprietor, respectively;

3. For a municipality, state, federal, or other public agency: either a principal executive officer or ranking elected official. For the purposes of this chapter, a principal executive officer of a federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a regional administrator of EPA); or

4. For Title IV affected sources:

- The designated representative insofar as actions, standards, requirements, or prohibitions under Title IV of the Act or the regulations promulgated thereunder are concerned; and

- The designated representative for any other purposes under this chapter or the Act.

“*Section 502(b)(10) changes*” are changes that contravene an express permit term and which are made pursuant to rule 567—22.110(455B). Such changes do not include changes that would violate applicable requirements or contravene federally enforceable permit terms and conditions that are monitoring (including test methods), record keeping, reporting, or compliance certification requirements.

“*State implementation plan (SIP)*” means the plan adopted by the state of Iowa and approved by the administrator which provides for implementation, maintenance, and enforcement of such primary and secondary ambient air quality standards as are adopted by the administrator, pursuant to the Act.

“*Stationary source*” means any building, structure, facility, or installation that emits or may emit any regulated air pollutant or any pollutant listed under Section 112(b) of the Act.

“*Stationary source categories*” means any of the following classes of sources:

1. Coal cleaning plants with thermal dryers;
2. Kraft pulp mills;
3. Portland cement plants;
4. Primary zinc smelters;
5. Iron and steel mills;
6. Primary aluminum ore reduction plants;
7. Primary copper smelters;
8. Municipal incinerators capable of charging more than 250 tons of refuse per day;
9. Hydrofluoric, sulfuric, or nitric acid plants;
10. Petroleum refineries;
11. Lime plants;
12. Phosphate rock processing plants;
13. Coke oven batteries;
14. Sulfur recovery plants;
15. Carbon black plants using the furnace process;
16. Primary lead smelters;
17. Fuel conversion plants;
18. Sintering plants;
19. Secondary metal production plants;
20. Chemical process plants — The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS code 325193 or 312140;
21. Fossil-fuel boilers, or combinations thereof, totaling more than 250 million Btu’s per hour heat input;
22. Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;
23. Taconite ore processing plants;
24. Glass fiber processing plants;
25. Charcoal production plants;
26. Fossil fuel-fired steam electric plants of more than 250 million Btu’s per hour heat input;

27. Any other stationary source category, which as of August 7, 1980, is regulated under Section 111 or 112 of the Act.

“*Subject to regulation*” means, for any air pollutant, that the pollutant is subject to either a provision in the Clean Air Act, or a nationally applicable regulation codified by the Administrator in 40 CFR Subchapter C (Air Programs) that requires actual control of the quantity of emissions of that pollutant, and that such a control requirement has taken effect and is operative to control, limit or restrict the quantity of emissions of that pollutant released from the regulated activity, except that:

1. Greenhouse gases (GHGs), the air pollutant defined in 40 CFR §86.1818-12(a) (as amended on May 7, 2010) as the aggregate group of six greenhouse gases that includes carbon dioxide, nitrous oxide, methane, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride, shall not be subject to regulation unless, as of July 1, 2011, the GHG emissions are at a stationary source emitting or having the potential to emit 100,000 tpy CO₂ equivalent emissions.

2. The term “tpy CO₂ equivalent emissions (CO₂e)” shall represent an amount of GHGs emitted and shall be computed by multiplying the mass amount of emissions (tpy) for each of the six greenhouse gases in the pollutant GHGs by the associated global warming potential of the gas published at 40 CFR Part 98, Subpart A, Table A-1, “Global Warming Potentials,” (as amended through December 24, 2014) and summing the resultant value for each to compute a tpy CO₂e.

For purposes of this definition, prior to July 21, 2014, the mass of the greenhouse gas carbon dioxide shall not include carbon dioxide emissions resulting from the combustion or decomposition of non-fossilized and biodegradable organic material originating from plants, animals, or micro-organisms (including products, by-products, residues and waste from agriculture, forestry and related industries as well as the non-fossilized and biodegradable organic fractions of industrial and municipal wastes, including gases and liquids recovered from the decomposition of non-fossilized and biodegradable organic material).

“*Title V permit*” means an operating permit under Title V of the Act.

“*12-month rolling period*” means a period of 12 consecutive months determined on a rolling basis with a new 12-month period beginning on the first day of each calendar month.

[ARC 9224B, IAB 11/17/10, effective 12/22/10; ARC 9906B, IAB 12/14/11, effective 11/16/11; ARC 0330C, IAB 9/19/12, effective 10/24/12; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—22.101(455B) Applicability of Title V operating permit requirements.

22.101(1) Except as provided in rule 567—22.102(455B), any person who owns or operates any of the following sources shall obtain a Title V operating permit and shall submit fees as required in 567—Chapter 30:

- a. Any affected source subject to the provisions of Title IV of the Act;
- b. Any major source;
- c. Any source, including any nonmajor source, subject to a standard, limitation, or other requirement under Section 111 of the Act (567—subrule 23.1(2), new source performance standards; 567—subrule 23.1(5), emission guidelines);
- d. Any source, including any area source, subject to a standard or other requirement under Section 112 of the Act (567—subrules 23.1(3) and 23.1(4), emission standards for hazardous air pollutants), except that a source is not required to obtain a Title V permit solely because it is subject to regulations or requirements under Section 112(r) of the Act;
- e. Any solid waste incinerator unit required to obtain a Title V permit under Section 129(e) of the Act;
- f. Any source category designated by the Administrator pursuant to 40 CFR 70.3 as amended through December 19, 2005.

22.101(2) Any nonmajor source required to obtain a Title V operating permit pursuant to subrule 22.101(1) is required to obtain a Title V permit only for the emissions units and related equipment causing the source to be subject to the Title V program.

22.101(3) Election to apply for permit. Rescinded IAB 7/19/06, effective 8/23/06.
[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—22.102(455B) Source category exemptions.

22.102(1) All sources listed in subrule 22.101(1) that are not major sources, affected sources subject to the provisions of Title IV of the Act or solid waste incineration units required to obtain a permit pursuant to Section 129(e) of the Act are exempt from the obligation to obtain a Title V permit until such time as the Administrator completes a rule making to determine how the program should be structured for nonmajor sources and the appropriateness of any permanent exemptions in addition to those provided for in subrule 22.102(3).

22.102(2) In the case of nonmajor sources subject to a standard or other requirement under either Section 111 or Section 112 of the Act after July 21, 1992, publication, the Administrator will determine at the time the new or amended standard is promulgated whether to exempt any or all such applicable sources from the requirement to obtain a Title V permit.

22.102(3) The following source categories are exempt from the obligation to obtain a Title V permit:

a. All sources and source categories that would be required to obtain a Title V permit solely because they are subject to 40 CFR 60, Subpart AAA, Standards of Performance for New Residential Wood Heaters, as amended through March 16, 2015;

b. All sources and source categories that would be required to obtain a Title V permit solely because they are subject to 40 CFR 61, Subpart M, National Emission Standard for Hazardous Air Pollutants for Asbestos, Section 61.145, Standard for Demolition and Renovation, as adopted by reference in 567—subrule 23.1(3);

c. All sources and source categories that would be required to obtain a Title V permit solely because they are subject to any of the following subparts from 40 CFR 63:

(1) Subpart M, National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities, as adopted by reference in 567—subrule 23.1(4).

(2) Subpart N, National Emission Standards for Chromium Emissions from Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks, as adopted by reference in 567—subrule 23.1(4).

(3) Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities, as adopted by reference in 567—subrule 23.1(4).

(4) Subpart T, National Emission Standards for Halogenated Solvent Cleaning, as adopted by reference in 567—subrule 23.1(4).

(5) Subpart RRR, National Emission Standards for Hazardous Air Pollutants for Secondary Aluminum Production, as adopted by reference in 567—subrule 23.1(4).

(6) Subpart VVV, National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works, as adopted by reference in 567—subrule 23.1(4).

[ARC 2949C, IAB 2/15/17, effective 3/22/17]

567—22.103(455B) Insignificant activities. The following are insignificant activities for purposes of the Title V application if not needed to determine the applicability of or to impose any applicable requirement. Title V permit emissions fees are not required from insignificant activities pursuant to 567—paragraph 30.4(2)“f.”

22.103(1) *Insignificant activities excluded from Title V operating permit application.* In accordance with 40 CFR 70.5 (as amended through October 6, 2009), these activities need not be included in the Title V permit application.

a. Mobile internal combustion and jet engines, marine vessels, and locomotives.

b. Equipment, other than anaerobic lagoons, used for cultivating land, harvesting crops, or raising livestock. This exemption is not applicable if the equipment is used to remove substances from grain which were applied to the grain by another person. This exemption also is not applicable to equipment used by a person to manufacture commercial feed, as defined in Iowa Code section 198.3, when that feed is normally not fed to livestock:

(1) Owned by that person or another person, and

(2) Located in a feedlot, as defined in Iowa Code section 172D.1(6), or in a confinement building owned or operated by that person, and

- (3) Located in this state.
- c.* Equipment or control equipment which eliminates all emissions to the atmosphere.
- d.* Equipment (other than anaerobic lagoons) or control equipment which emits odors unless such equipment or control equipment also emits particulate matter or any other air pollutant or contaminant.
- e.* Air conditioning or ventilating equipment not designed to remove air contaminants generated by or released from associated equipment.
- f.* Residential wood heaters, cookstoves, or fireplaces.
- g.* The equipment in laboratories used exclusively for nonproduction chemical and physical analyses. Nonproduction analyses means analyses incidental to the production of a good or service and includes analyses conducted for quality assurance or quality control activities, or for the assessment of environmental impact.
- h.* Recreational fireplaces.
- i.* Barbecue pits and cookers except at a meat packing plant or a prepared meat manufacturing facility.
- j.* Stacks or vents to prevent escape of sewer gases through plumbing traps for systems handling domestic sewage only. Systems which include any industrial waste are not exempt.
- k.* Retail gasoline and diesel fuel handling facilities.
- l.* Photographic process equipment by which an image is reproduced upon material sensitized to radiant energy.
- m.* Equipment used for hydraulic or hydrostatic testing.
- n.* General vehicle maintenance and servicing activities at the source, other than gasoline fuel handling.
- o.* Cafeterias, kitchens, and other facilities used for preparing food or beverages primarily for consumption at the source.
- p.* Equipment using water, water and soap or detergent, or a suspension of abrasives in water for purposes of cleaning or finishing provided no organic solvent has been added to the water, the boiling point of the additive is not less than 100°C (212°F), and the water is not heated above 65.5°C (150°F).
- q.* Administrative activities including, but not limited to, paper shredding, copying, photographic activities, and blueprinting machines. This does not include incinerators.
- r.* Laundry dryers, extractors, and tumblers processing clothing, bedding, and other fabric items used at the source that have been cleaned with water solutions of bleach or detergents provided that any organic solvent present in such items before processing that is retained from cleanup operations shall be addressed as part of the volatile organic compound emissions from use of cleaning materials.
- s.* Housekeeping activities for cleaning purposes, including collecting spilled and accumulated materials at the source, but not including use of cleaning materials that contain organic solvent.
- t.* Refrigeration systems, including storage tanks used in refrigeration systems, but excluding any combustion equipment associated with such systems.
- u.* Activities associated with the construction, on-site repair, maintenance or dismantlement of buildings, utility lines, pipelines, wells, excavations, earthworks and other structures that do not constitute emission units.
- v.* Storage tanks of organic liquids with a capacity of less than 500 gallons, provided the tank is not used for storage of any material listed as a hazardous air pollutant pursuant to Section 112(b) of the Clean Air Act.
- w.* Piping and storage systems for natural gas, propane, and liquified petroleum gas, excluding pipeline compressor stations and associated storage facilities.
- x.* Water treatment or storage systems, as follows:
 - (1) Systems for potable water or boiler feedwater.
 - (2) Systems, including cooling towers, for process water provided that such water has not been in direct or indirect contact with process steams that contain volatile organic material or materials listed as hazardous air pollutants pursuant to Section 112(b) of the Clean Air Act.
- y.* Lawn care, landscape maintenance, and groundskeeping activities.

z. Containers, reservoirs, or tanks used exclusively in dipping operations to coat objects with oils, waxes, or greases, provided no organic solvent has been mixed with such materials.

aa. Cold cleaning degreasers that are not in-line cleaning machines, where the vapor pressure of the solvents used never exceeds 2 kPa (15 mmHg or 0.3 psi) measured at 38°C (100°F) or 0.7 kPa (5 mmHg or 0.1 psi) at 20°C (68°F). (Note: Cold cleaners subject to 40 CFR Part 63 Subpart T are not considered insignificant activities.)

bb. Manually operated equipment used for buffing, polishing, carving, cutting, drilling, machining, routing, sanding, sawing, scarfing, surface grinding or turning.

cc. Use of consumer products, including hazardous substances as that term is defined in the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.), when the product is used at a source in the same manner as normal consumer use.

dd. Activities directly used in the diagnosis and treatment of disease, injury or other medical condition.

ee. Firefighting activities and training in preparation for fighting fires conducted at the source. (Note: Written notification pursuant to 567—paragraph 23.2(3) “g” is required at least ten working days before such action commences.)

ff. Activities associated with the construction, repair or maintenance of roads or other paved or open areas, including operation of street sweepers, vacuum trucks, spray trucks and other vehicles related to the control of fugitive emissions of such roads or other areas.

gg. Storage and handling of drums or other transportable containers when the containers are sealed during storage and handling.

hh. Individual points of emission or activities as follows:

(1) Individual flanges, valves, pump seals, pressure relief valves and other individual components that have the potential for leaks.

(2) Individual sampling points, analyzers, and process instrumentation, whose operation may result in emissions.

(3) Individual features of an emission unit such as each burner and sootblower in a boiler or each use of cleaning materials on a coating or printing line.

ii. Construction activities at a source solely associated with the modification or building of a facility, an emission unit or other equipment at the source. (Note: Notwithstanding the status of this activity as insignificant, a particular activity that entails modification or construction of an emission unit or construction of air pollution control equipment may require a construction permit pursuant to 22.1(455B) and may subsequently require a revised Title V operating permit. A revised Title V operating permit may also be necessary for operation of an emission unit after completion of a particular activity if the existing Title V operating permit does not accommodate the new state of the emission unit.)

jj. Activities at a source associated with the maintenance, repair, or dismantlement of an emission unit or other equipment installed at the source, including preparation for maintenance, repair or dismantlement, and preparation for subsequent startup, including preparation of a shutdown vessel for entry, replacement of insulation, welding and cutting, and steam purging of a vessel prior to startup.

22.103(2) *Insignificant activities which must be included in Title V operating permit applications.*

a. The following are insignificant activities based on potential emissions:

An emission unit which has the potential to emit less than:

5 tons per year of any regulated air pollutant, except:

2.5 tons per year of PM₁₀,

0.52 tons per year of PM_{2.5} (does not apply to emission units for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013),

2 lbs per year of lead or lead compounds (40 lbs per year for emission units for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013),

2500 lbs per year of any combination of hazardous air pollutants except high-risk pollutants,

1000 lbs per year of any individual hazardous air pollutant except high-risk pollutants,

250 lbs per year of any combination of high-risk pollutants, or
100 lbs per year of any individual high-risk pollutant.

The definition of “high-risk pollutant” is found in rule 567—22.100(455B).

b. The following are insignificant activities:

(1) Fuel-burning equipment for indirect heating and reheating furnaces or indirect cooling units using natural or liquefied petroleum gas with a capacity of less than 10 million Btu per hour input per combustion unit.

(2) Fuel-burning equipment for indirect heating or indirect cooling for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013, with a capacity of less than 1 million Btu per hour input per combustion unit when burning coal, untreated wood, or fuel oil.

Fuel-burning equipment for indirect heating or indirect cooling for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, with a capacity of less than 1 million Btu per hour input per combustion unit when burning untreated wood, untreated seeds or pellets, other untreated vegetative materials, or fuel oil provided that the equipment and the fuel meet the condition specified in this subparagraph (22.103(2)“b”(2)). Used oils meeting the specification from 40 CFR 279.11 as amended through July 14, 2006, are acceptable fuels. When combusting used oils, the equipment must have a maximum rated capacity of 50,000 Btu or less per hour of heat input or a maximum throughput of 3600 gallons or less of used oils per year. When combusting untreated wood, untreated seeds or pellets, or other untreated vegetative materials, the equipment must have a maximum rated capacity of 265,600 Btu or less per hour or a maximum throughput of 378,000 pounds or less per year of each fuel or any combination of fuels.

(3) Incinerators with a rated refuse burning capacity of less than 25 pounds per hour for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred on or before October 23, 2013. Incinerators for which initiation of construction, installation, reconstruction, or alteration (as defined in rule 567—20.2(455B)) occurred after October 23, 2013, shall not qualify as an insignificant activity. After October 23, 2013, only paint clean-off ovens with a maximum rated capacity of less than 25 pounds per hour that do not combust lead-containing materials shall qualify as an insignificant activity.

(4) Gasoline, diesel fuel, or oil storage tanks with a capacity of 1,000 gallons or less and an annual throughput of less than 40,000 gallons.

(5) A storage tank which contains no volatile organic compounds above a vapor pressure of 0.75 pounds per square inch at the normal operating temperature of the tank when other emissions from the tank do not exceed the levels in paragraph 22.103(2)“a.”

(6) Internal combustion engines that are used for emergency response purposes with a brake horsepower rating of less than 400 measured at the shaft. The manufacturer’s nameplate rating at full load shall be defined as the brake horsepower output at the shaft. Emergency engines that are subject to any of the following federal regulations are not considered to be insignificant activities for purposes of this rule (567—22.103(455B)):

1. New source performance standards (NSPS) for stationary compression ignition internal combustion engines (40 CFR Part 60, Subpart IIII);

2. New source performance standards (NSPS) for stationary spark ignition internal combustion engines (40 CFR Part 60, Subpart JJJJ); or

3. National emission standards for hazardous air pollutants (NESHAP) for reciprocating internal combustion engines (40 CFR Part 63, Subpart ZZZZ).

[ARC 1013C, IAB 9/18/13, effective 10/23/13; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; Editorial change: IAC Supplement 5/9/18]

567—22.104(455B) Requirement to have a Title V permit. No source may operate after the time that it is required to submit a timely and complete application, except in compliance with a properly issued Title V operating permit. However, if a source submits a timely and complete application for permit issuance (including renewal), the source’s failure to have a permit is not a violation of this chapter until

the director takes final action on the permit application, except as noted in this rule. In that case, all terms and conditions of the permit shall remain in effect until the renewal permit has been issued or denied.

22.104(1) This protection shall cease to apply if, subsequent to the completeness determination, the applicant fails to submit, by the deadline specified in writing by the director, any additional information identified as being needed to process the application.

22.104(2) Sources making permit revisions pursuant to rule 567—22.110(455B) shall not be in violation of this rule.

567—22.105(455B) Title V permit applications.

22.105(1) Duty to apply. For each source required to obtain a Title V operating permit, the owner or operator or designated representative, where applicable, shall present or mail a complete and timely permit application in accordance with this rule to the following locations: Iowa Department of Natural Resources, Air Quality Bureau, 502 East 9th Street, Des Moines, Iowa 50319 (one copy); and U.S. EPA Region VII, 11201 Renner Boulevard, Lenexa, Kansas 66219 (one copy); and, if applicable, the local permitting authority, which is either Linn County Public Health Department, Air Quality Division, 501 13th Street NW, Cedar Rapids, Iowa 52405 (one copy); or Polk County Public Works, Air Quality Division, 5885 NE 14th Street, Des Moines, Iowa 50313 (one copy). Application submission methods may include, but are not limited to, U.S. Postal Service, private parcel delivery services, or hand delivery. Applications are not required to be submitted by certified mail. Alternatively, an owner or operator may submit a complete and timely application through the electronic submittal format specified by the department. An owner or operator of a source required to obtain a Title V permit pursuant to subrule 22.101(1) shall submit all required fees as required in 567—Chapter 30.

a. Timely application. Each owner or operator applying for a Title V permit shall submit an application as follows:

(1) Initial application for an existing source. The owner or operator of a stationary source that was existing on or before April 20, 1994, shall make the first time submittals of a Title V permit application to the department by November 15, 1994. However, the owner or operator may choose to defer submittal of Part 2 of the permit application until December 31, 1995. The department will mail notice of the deadline for Part 2 of the permit application to all applicants who have filed Part 1 of the application by October 17, 1995.

(2) Initial application for a new source. The owner or operator of a stationary source that commenced construction or reconstruction after April 20, 1994, or that otherwise became subject to the requirement to obtain a Title V permit after April 20, 1994, shall submit an application to the department within 12 months of becoming subject to the Title V permit requirements.

(3) Application related to 112(g), PSD or nonattainment. The owner or operator of a stationary source that is subject to Section 112(g) of the Act, that is subject to rule 567—22.4(455B) or 567—33.3(455B) (prevention of significant deterioration (PSD)), or that is subject to rule 567—22.5(455B) or 567—31.3(455B) (nonattainment area permitting) shall submit an application to the department within 12 months of commencing operation. In cases in which an existing Title V permit would prohibit such construction or change in operation, the owner or operator must obtain a Title V permit revision before commencing operation.

(4) Renewal application. The owner or operator of a stationary source with a Title V permit shall submit an application to the department for a permit renewal at least 6 months prior to, but not more than 18 months prior to, the date of permit expiration.

(5) Changes allowed without a permit revision (off-permit revision). The owner or operator of a stationary source with a Title V permit who is proposing a change that is allowed without a Title V permit revision (an off-permit revision) as specified in rule 567—22.110(455B) shall submit to the department a written notification as specified in rule 567—22.110(455B) at least 30 days prior to the proposed change.

(6) Application for an administrative permit amendment. Prior to implementing a change that satisfies the requirements for an administrative permit amendment as set forth in rule 567—22.111(455B), the owner or operator shall submit to the department an application for an administrative amendment as specified in rule 567—22.111(455B).

(7) Application for a minor permit modification. Prior to implementing a change that satisfies the requirements for a minor permit modification as set forth in rule 567—22.112(455B), the owner or operator shall submit to the department an application for a minor permit modification as specified in rule 567—22.112(455B).

(8) Application for a significant permit modification. The owner or operator of a source that satisfies the requirements for a significant permit modification as set forth in rule 567—22.113(455B) shall submit to the department an application for a significant permit modification as specified in rule 567—22.113(455B) within three months after the commencing operation of the changed source. However, if the existing Title V permit would prohibit such construction or change in operation, the owner or operator shall not commence operation of the changed source until the department issues a revised Title V permit that allows the change.

(9) Application for an acid rain permit. The owner or operator of a source subject to the acid rain program, as set forth in rules 567—22.120(455B) through 567—22.148(455B), shall submit an application for an initial Phase II acid rain permit by January 1, 1996 (for sulfur dioxide), or by January 1, 1998 (for nitrogen oxides).

b. Complete application. To be deemed complete, an application must provide all information required pursuant to subrule 22.105(2), except that applications for permit revision need supply such information only if it is related to the proposed change.

22.105(2) Standard application form and required information. To apply for a Title V permit, applicants shall complete the standard permit application form available only from the department and supply all information required by the filing instructions found on that form. The information submitted must be sufficient to evaluate the source and its application and to determine all applicable requirements and to evaluate the fee amount required by rule 567—30.4(455B). If a source is not a major source and is applying for a Title V operating permit solely because of a requirement imposed by paragraphs 22.101(1)“c” and “d,” then the information provided in the operating permit application may cover only the emissions units that trigger Title V applicability. The applicant shall submit the information called for by the application form for each emissions unit to be permitted, except for activities which are insignificant according to the provisions of rule 567—22.103(455B). The applicant shall provide a list of all insignificant activities and specify the basis for the determination of insignificance for each activity. Nationally standardized forms shall be used for the acid rain portions of permit applications and compliance plans, as required by regulations promulgated under Title IV of the Act. The standard application form and any attachments shall require that the following information be provided:

a. Identifying information, including company name and address (or plant or source name if different from the company name), owner’s name and agent, and telephone number and names of plant site manager/contact.

b. A description of the source’s processes and products (by two-digit Standard Industrial Classification Code) including any associated with each alternate scenario identified by the applicant.

c. The following emissions-related information shall be submitted to the department on the emissions inventory portion of the application, unless the department notifies the applicant that the emissions-related information is not required because it has already been submitted:

(1) All emissions of pollutants for which the source is major, and all emissions of regulated air pollutants. The permit application shall describe all emissions of regulated air pollutants emitted from any emissions unit except where such units are exempted. The source shall submit additional information related to the emissions of air pollutants sufficient to verify which requirements are applicable to the source, and other information necessary to collect any permit fees owed under the approved fee schedule.

(2) Identification and description of all points of emissions in sufficient detail to establish the basis for fees and the applicability of any and all requirements.

(3) Emissions rates in tons per year and in such terms as are necessary to establish compliance consistent with the applicable standard reference test method, if any.

(4) The following information to the extent it is needed to determine or regulate emissions: fuels, fuel use, raw materials, production rates, and operating schedules.

(5) Identification and description of air pollution control equipment.

- (6) Identification and description of compliance monitoring devices or activities.
- (7) Limitations on source operations affecting emissions or any work practice standards, where applicable, for all regulated pollutants.
- (8) Other information required by any applicable requirement (including information related to stack height limitations developed pursuant to Section 123 of the Act).
- (9) Calculations on which the information in subparagraphs (1) to (8) above is based.
- (10) Fugitive emissions from a source shall be included in the permit application in the same manner as stack emissions, regardless of whether the source category in question is included in the list of sources contained in the definition of major source.
 - d.* The following air pollution control requirements:
 - (1) Citation and description of all applicable requirements, and
 - (2) Description of or reference to any applicable test method for determining compliance with each applicable requirement.
 - e.* Other specific information that may be necessary to implement and enforce other applicable requirements of the Act or of these rules or to determine the applicability of such requirements.
 - f.* An explanation of any proposed exemptions from otherwise applicable requirements.
 - g.* Additional information as determined to be necessary by the director to define alternative operating scenarios identified by the source pursuant to subrule 22.108(12) or to define permit terms and conditions relating to operational flexibility and emissions trading pursuant to subrule 22.108(11) and rule 567—22.112(455B).
 - h.* A compliance plan that contains the following:
 - (1) A description of the compliance status of the source with respect to all applicable requirements.
 - (2) The following statements regarding compliance status: For applicable requirements with which the stationary source is in compliance, a statement that the stationary source will continue to comply with such requirements. For applicable requirements that will become effective during the permit term, a statement that the stationary source will meet such requirements on a timely basis. For requirements for which the stationary source is not in compliance at the time of permit issuance, a narrative description of how the stationary source will achieve compliance with such requirements.
 - (3) A compliance schedule that contains the following:
 1. For applicable requirements with which the stationary source is in compliance, a statement that the stationary source will continue to comply with such requirements. For applicable requirements that will become effective during the permit term, a statement that the stationary source will meet such requirements on a timely basis. A statement that the stationary source will meet in a timely manner applicable requirements that become effective during the permit term shall satisfy this provision, unless a more detailed schedule is expressly required by the applicable requirement.
 2. A compliance schedule for sources that are not in compliance with all applicable requirements at the time of permit issuance. Such a schedule shall include a schedule of remedial measures, including an enforceable sequence of actions with milestones, leading to compliance with any applicable requirements for which the stationary source will be in noncompliance at the time of permit issuance.
 3. This compliance schedule shall resemble and be at least as stringent as any compliance schedule contained in any judicial consent decree or administrative order to which the source is subject. Any compliance schedule shall be supplemental to, and shall not sanction noncompliance with, the applicable requirements on which it is based.
 - (4) A schedule for submission of certified progress reports no less frequently than every six months for sources required to have a compliance schedule in the permit.
 - i.* Requirements for compliance certification, including the following:
 - (1) A certification of compliance for the prior year with all applicable requirements certified by a responsible official consistent with subrule 22.107(4) and Section 114(a)(3) of the Act.
 - (2) A statement of methods used for determining compliance, including a description of monitoring, record keeping, and reporting requirements and test methods.
 - (3) A schedule for submission of compliance certifications for each compliance period (one year unless required for a shorter time period by an applicable requirement) during the permit term, which

shall be submitted annually, or more frequently if required by an underlying applicable requirement or by the director.

(4) A statement indicating the source's compliance status with any applicable enhanced monitoring and compliance certification requirements of the Act.

(5) Notwithstanding any other provisions of these rules, for the purposes of submission of compliance certifications, an owner or operator is not prohibited from using monitoring as required by subrules 22.108(3), 22.108(4) or 22.108(5) and incorporated into a Title V operating permit in addition to any specified compliance methods.

j. The compliance plan content requirements specified in these rules shall apply and be included in the acid rain portion of a compliance plan for a Title IV affected source, except as specifically superseded by regulations promulgated under Title IV of the Act, with regard to the schedule and method(s) the source shall use to achieve compliance with the acid rain emissions limitations.

22.105(3) Hazardous air pollutant early reduction application. Anyone requesting a compliance extension from a standard issued under Section 112(d) of the Act must submit with its Title V permit application information that complies with the requirements established in 567—paragraph 23.1(4) “d.”

22.105(4) Acid rain application content. The acid rain application content shall be as prescribed in the acid rain rules found at rules 567—22.128(455B) and 567—22.129(455B).

22.105(5) More than one Title V operating permit for a stationary source. Following application made pursuant to subrule 22.105(1), the department may, at its discretion, issue more than one Title V operating permit for a stationary source, provided that the owner or operator does not have, and does not propose to have, a sourcewide emission limit or a sourcewide alternative operating scenario.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3440C, IAB 11/8/17, effective 12/13/17; ARC 4335C, IAB 3/13/19, effective 4/17/19]

567—22.106(455B) Annual Title V emissions inventory.

22.106(1) Emissions fee. Fees shall be paid as set forth in 567—Chapter 30.

22.106(2) Emissions inventory and documentation due dates. The emissions inventory shall be submitted through the electronic format specified by the department.

An owner or operator shall, by March 31, submit documentation of actual emissions for the previous calendar year.

The department shall calculate the total statewide Title V emissions for the prior calendar year and make this information available to the public no later than April 30 of each year.

22.106(3) Correction of errors. If an owner or operator, or the department, finds an error in a Title V emissions inventory, the owner or operator shall submit to the department revised forms making the necessary corrections to the Title V emissions inventory. Corrected forms shall be submitted as soon as possible after the errors are discovered or upon notification by the department.

[ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19]

567—22.107(455B) Title V permit processing procedures.

22.107(1) Action on application.

a. Conditions for action on application. A permit, permit modification, or renewal may be issued only if all of the following conditions have been met:

(1) The permitting authority has received a complete application for a permit, permit modification, or permit renewal, except that a complete application need not be received before issuance of a general permit under rule 567—22.109(455B);

(2) Except for modifications qualifying for minor permit modification procedures under rule 22.112(455B), the permitting authority has complied with the requirements for public participation under subrule 22.107(6);

(3) The permitting authority has complied with the requirements for notifying and responding to affected states under subrule 22.107(7);

(4) The conditions of the permit provide for compliance with all applicable requirements and the requirements of this chapter;

(5) The administrator has received a copy of the proposed permit and any notices required under subrule 22.107(7), and has not objected to issuance of the permit under subrule 22.107(7) within the time period specified therein;

(6) If the administrator has properly objected to the permit pursuant to the provisions of 40 CFR 70.8(d) as amended to July 21, 1992, or subrule 22.107(7), then the permitting authority may issue a permit only after the administrator's objection has been resolved; and

(7) No permit for a solid waste incineration unit combusting municipal waste subject to the provisions of Section 129(e) of the Act may be issued by an agency, instrumentality or person that is also responsible, in whole or part, for the design and construction or operation of the unit.

b. Time for action on application. The permitting authority shall take final action on each complete permit application (including a request for permit modification or renewal) within 18 months of receiving a complete application, except in the following instances:

(1) When otherwise provided under Title V or Title IV of the Act for the permitting of affected sources under the acid rain program.

(2) In the case of initial permit applications, the permitting authority may take up to three years from the effective date of the program to take final action on an application.

(3) Any complete permit applications containing an early reduction demonstration under Section 112(i)(5) of the Act shall be acted upon within nine months of receipt of the complete application.

c. Prioritization of applications. The director shall give priority to action on Title V applications involving construction or modification for which a construction permit pursuant to subrule 22.1(1) or Title I of the Act, Parts C and D, is also required. The director also shall give priority to action on Title V applications involving early reduction of hazardous air pollutants pursuant to 567—paragraph 23.1(4) “d.”

d. Completeness of applications. The department shall promptly provide notice to the applicant of whether the application is complete. Unless the permitting authority requests additional information or otherwise notifies the applicant of incompleteness within 60 days of receipt of an application, the application shall be deemed complete. If, while processing an application that has been determined to be complete, the permitting authority determines that additional information is necessary to evaluate or take final action on that application, the permitting authority may request in writing such information and set a reasonable deadline for a response. The source's ability to operate without a permit, as set forth in rule 567—22.104(455B), shall be in effect from the date the application is determined to be complete until the final permit is issued, provided that the applicant submits any requested additional information by the deadline specified by the permitting authority. For modifications processed through minor permit modification procedures, a completeness determination shall not be required.

e. Decision to deny a permit application. The director shall decide to issue or deny the permit. The director shall notify the applicant as soon as practicable that the application has been denied. Upon denial of the permit the provisions of paragraph 22.107(1) “d” shall no longer be applicable. The new application shall be regarded as an entirely separate application containing all the required information and shall not depend on references to any documents contained in the previous denied application.

f. Fact sheet. A draft permit and fact sheet shall be prepared by the permitting authority. The fact sheet shall include the rationale for issuance or denial of the permit; a brief description of the type of facility; a summary of the type and quantity of air pollutants being emitted; a brief summary of the legal and factual basis for the draft permit conditions, including references to applicable statutes and rules; a description of the procedures for reaching final decision on the draft permit including the comment period, the address where comments will be received, and procedures for requesting a hearing and the nature of the hearing; and the name and telephone number for a person to contact for additional information. The permitting authority shall provide the fact sheet to EPA and to any other person who requests it.

g. Relation to construction permits. The submittal of a complete application shall not affect the requirement that any source have a construction permit under Title I of the Act and subrule 22.1(1).

22.107(2) Confidential information. If a source has submitted information with an application under a claim of confidentiality to the department, the source shall also submit a copy of such information directly to the administrator. Requests for confidentiality must comply with 561—Chapter 2.

22.107(3) Duty to supplement or correct application. Any applicant who fails to submit any relevant facts or who has submitted incorrect information in a permit application shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrected information. In addition, an applicant shall provide additional information as necessary to address any requirements that become applicable to the source after the date the source filed a complete application but prior to release of a draft permit. Applicants who have filed a complete application shall have 60 days following notification by the department to file any amendments. Any MACT determinations in permit applications will be evaluated based on the standards, limitations or levels of technology existing on the date the initial application is deemed complete.

22.107(4) Certification of truth, accuracy, and completeness. Any application form, report, or compliance certification submitted pursuant to these rules shall contain certification by a responsible official of truth, accuracy, and completeness. This certification and any other certification required under these rules shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

22.107(5) Early reduction application evaluation. Hazardous air pollutant early reduction application evaluation review shall follow the procedures established in 567—paragraph 23.1(4) “d.”

22.107(6) Public notice and public participation.

a. The permitting authority shall provide public notice and an opportunity for public comments, including an opportunity for a hearing, before taking any of the following actions: issuance, denial or renewal of a permit; or significant modification or revocation or reissuance of a permit.

b. Notice shall be given by posting of the notice, including the draft permit, for the duration of the public comment period on a public website identified by the permitting authority and designed to give general public notice. Notice also shall be given to persons on a mailing list developed by the permitting authority, including those who request in writing to be on the list. The department may use other means if necessary to ensure adequate notice to the affected public.

c. The public notice shall include the following:

- (1) Identification of the Title V source.
- (2) Name and address of the permittee.
- (3) Name and address of the permitting authority processing the permit.
- (4) The activity or activities involved in the permit action.
- (5) The emissions change involved in any permit modification.
- (6) The air pollutants or contaminants to be emitted.
- (7) The time and place of any possible public hearing.
- (8) A statement that any person may submit written and signed comments, or may request a public hearing, or both, on the proposed permit. A statement of procedures to request a public hearing shall be included.

(9) The name, address, and telephone number of a person from whom additional information may be obtained. Information entitled to confidential treatment pursuant to Section 114(c) of the Act or state law shall not be released pursuant to this provision. However, the contents of a Title V permit shall not be entitled to protection under Section 114(c) of the Act.

(10) Locations where copies of the permit application and the proposed permit may be reviewed, including the closest department office, and the times at which they shall be available for public inspection.

d. At least 30 days shall be provided for public comment. Notice of any public hearing shall be given at least 30 days in advance of the hearing.

e. Any person may request a public hearing. A request for a public hearing shall be in writing and shall state the person’s interest in the subject matter and the nature of the issues proposed to be raised at

the hearing. The director shall hold a public hearing upon finding, on the basis of requests, a significant degree of relevant public interest in a draft permit. A public hearing also may be held at the director's discretion.

f. The director shall keep a record of the commenters and of the issues raised during the public participation process and shall prepare written responses to all comments received. At the time a final decision is made, the record and copies of the director's responses shall be made available to the public.

g. The permitting authority shall provide notice and opportunity for participation by affected states as provided by subrule 22.107(7).

22.107(7) Permit review by EPA and affected states.

a. Transmission of information to the administrator. Except as provided in subrule 22.107(2) or waived by the administrator, the director shall provide to the administrator a copy of each permit application or modification application, including any attachments and compliance plans; each proposed permit; and each final permit. For purposes of this subrule, the application information may be submitted in a computer-readable format compatible with the administrator's national database management system.

b. Review by affected states. The director shall provide notice of each draft permit to any affected state on or before the time that public notice is provided to the public pursuant to subrule 22.107(6), except to the extent that subrule 22.112(3) requires the timing of the notice to be different. If the director refuses to accept a recommendation of any affected state, submitted during the public or affected state review period, then the director shall notify the administrator and the affected state in writing. The notification shall include the director's reasons for not accepting the recommendation(s). The director shall not be required to accept recommendations that are not based on applicable requirements.

c. EPA objection. No permit for which an application must be transmitted to the administrator shall be issued if the administrator objects in writing to its issuance as not in compliance with the applicable requirements within 45 days after receiving a copy of the proposed permit and necessary supporting information under 22.107(7) "a." Within 90 days after the date of an EPA objection made pursuant to this rule, the director shall submit a response to the objection, if the objection has not been resolved.

22.107(8) Public petitions to the administrator regarding Title V permits.

a. If the administrator does not object to a proposed permit, any person may petition the administrator within 60 days after the expiration of the administrator's 45-day review period to make an objection pursuant to 40 CFR 70.8(d) as amended to July 21, 1992.

b. Any person who petitions the administrator pursuant to the provisions of 40 CFR 70.8(d) as amended to July 21, 1992, shall notify the department by certified mail of such petition immediately, and in no case more than 10 days following the date the petition is submitted to EPA. Such notice shall include a copy of the petition submitted to EPA and a separate written statement detailing the grounds for the objection(s) and whether the objection(s) was raised during the public comment period. A petition for review shall not stay the effectiveness of a permit or its requirements if the permit was issued after the end of the 45-day EPA review period and prior to the administrator's objection.

c. If the administrator objects to the permit as a result of a petition filed pursuant to 40 CFR 70.8(d) as amended to July 21, 1992, then the director shall not issue a permit until the administrator's objection has been resolved. However, if the director has issued a permit prior to receipt of the administrator's objection, and the administrator modifies, terminates, or revokes such permit, consistent with the procedures in 40 CFR 70.7 as amended to July 21, 1992, then the director may thereafter issue only a revised permit that satisfies the administrator's objection. In any case, the source shall not be in violation of the requirement to have submitted a timely and complete application.

22.107(9) A Title V permit application may be denied if:

a. The director finds that a source is not in compliance with any applicable requirement; or

b. An applicant knowingly submits false information in a permit application.

22.107(10) Retention of permit records. The director shall keep all records associated with each permit for a minimum of five years.

[ARC 3679C, IAB 3/14/18, effective 4/18/18]

567—22.108(455B) Permit content. Each Title V permit shall include the following elements:

22.108(1) Enforceable emission limitations and standards. Each permit issued pursuant to this chapter shall include emissions limitations and standards, including those operational requirements and limitations that ensure compliance with all applicable requirements at the time of permit issuance.

a. The permit shall specify and reference the origin of and authority for each term or condition and identify any difference in form as compared to the applicable requirement upon which the term or condition is based.

b. The permit shall state that, where an applicable requirement of the Act is more stringent than an applicable requirement of regulations promulgated under Title IV of the Act, both provisions shall be incorporated into the permit and shall be enforceable by the administrator.

c. If an applicable implementation plan allows a determination of an alternative emission limit at a Title V source, equivalent to that contained in the plan, to be made in the permit issuance, renewal, or significant modification process, and the state elects to use such process, then any permit containing such equivalency determination shall contain provisions to ensure that any resulting emissions limit has been demonstrated to be quantifiable, accountable, enforceable, and based on replicable procedures.

d. If an early reduction demonstration is approved as part of the Title V permit application, the permit shall include enforceable alternative emissions limitations for the source reflecting the reduction which qualified the source for the compliance extension.

e. Fugitive emissions from a source shall be included in the permit in the same manner as stack emissions, regardless of whether the source category in question is included in the list of sources contained in the definition of major source.

f. For all major sources, all applicable requirements for all relevant emissions units in the major source shall be included in the permit.

22.108(2) Permit duration. The permit shall specify a fixed term not to exceed five years except:

a. Permits issued to Title IV affected sources shall have a fixed term of five years.

b. Permits issued to solid waste incineration units combusting municipal waste subject to standards under Section 129(e) of the Act shall have a term not to exceed 12 years. Such permits shall be reviewed every five years.

22.108(3) Monitoring. Each permit shall contain the following requirements with respect to monitoring:

a. All emissions monitoring and analysis procedures or test methods required under the applicable requirements, including any procedures and methods promulgated pursuant to Section 114(a)(3) or 504(b) of the Act;

b. Where the applicable requirement does not require periodic testing or instrumental or noninstrumental monitoring (which may consist of record keeping designed to serve as monitoring), periodic monitoring sufficient to yield reliable data from the relevant time period that are representative of the source's compliance with the permit, as reported pursuant to subrule 22.108(5). Such monitoring shall be determined by application of the "Periodic Monitoring Guidance" (as amended through October 24, 2012) available from the department;

c. As necessary, requirements concerning the use, maintenance, and, where appropriate, installation of monitoring equipment or methods; and

d. As required, Compliance Assurance Monitoring (CAM) consistent with 40 CFR Part 64 (as amended through October 22, 1997).

22.108(4) Record keeping. With respect to record keeping, the permit shall incorporate all applicable record-keeping requirements and require, where applicable, the following:

a. Records of required monitoring information that include the following:

(1) The date, place as defined in the permit, and time of sampling or measurements;

(2) The date(s) the analyses were performed;

(3) The company or entity that performed the analyses;

(4) The analytical techniques or methods used;

(5) The results of such analyses; and

(6) The operating conditions as existing at the time of sampling or measurement; and

b. Retention of records of all required monitoring data and support information for a period of at least five years from the date of the monitoring sample, measurement, report, or application. Support information includes all calibration and maintenance records and all original strip-chart and other recordings for continuous monitoring instrumentation, and copies of all reports required by the permit.

22.108(5) Reporting. With respect to reporting, the permit shall incorporate all applicable reporting requirements and shall require the following:

a. Submittal of reports of any required monitoring at least every six months. All instances of deviations from permit requirements must be clearly identified in such reports. All required reports must be certified by a responsible official consistent with subrule 22.107(4).

b. Prompt reporting of deviations from permit requirements, including those attributable to upset conditions as defined in the permit, the probable cause of such deviations, and any corrective actions or preventive measures taken. The director shall define “prompt” in relation to the degree and type of deviation likely to occur and the applicable requirements.

22.108(6) Risk management plan. Pursuant to Section 112(r)(7)(E) of the Act, if the source is required to develop and register a risk management plan pursuant to Section 112(r) of the Act, the permit shall state the requirement for submission of the plan to the air quality bureau of the department. The permit shall also require filing the plan with appropriate authorities and an annual certification to the department that the plan is being properly implemented.

22.108(7) A permit condition prohibiting emissions exceeding any allowances that the affected source lawfully holds under Title IV of the Act or the regulations promulgated thereunder.

a. No permit revision shall be required for increases in emissions that are authorized by allowances acquired pursuant to the acid rain program, provided that such increases do not require a permit revision under any other applicable requirement.

b. No limit shall be placed on the number of allowances held by the Title IV affected source. The Title IV affected source may not, however, use allowances as a defense to noncompliance with any other applicable requirement.

c. Any such allowances shall be accounted for according to the procedures established in regulations promulgated under Title IV of the Act.

d. Any permit issued pursuant to the requirements of these rules and Title V of the Act to a unit subject to the provisions of Title IV of the Act shall include conditions prohibiting all of the following:

(1) Annual emissions of sulfur dioxide in excess of the number of allowances to emit sulfur dioxide held by the owners or operators of the unit or the designated representative of the owners or operators.

(2) Exceedences of applicable emission rates.

(3) The use of any allowance prior to the year for which it was allocated.

(4) Contravention of any other provision of the permit.

22.108(8) Severability clause. The permit shall contain a severability clause to ensure the continued validity of the various permit requirements in the event of a challenge to any portions of the permit.

22.108(9) Other provisions. The Title V permit shall contain provisions stating the following:

a. The permittee must comply with all conditions of the Title V permit. Any permit noncompliance constitutes a violation of the Act and is grounds for enforcement action; for a permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

b. Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of the permit.

c. The permit may be modified, revoked, reopened, and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any permit condition.

d. The permit does not convey any property rights of any sort, or any exclusive privilege.

e. The permittee shall furnish to the director, within a reasonable time, any information that the director may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit or to determine compliance with the permit. Upon request, the permittee also shall furnish to the director copies of records required to be kept by the permit or, for information claimed

to be confidential, the permittee shall furnish such records directly to the administrator of EPA along with a claim of confidentiality.

22.108(10) Fees. The permit shall include a provision to ensure that the Title V permittee pays fees to the director pursuant to rule 567—30.4(455B).

22.108(11) Emissions trading. A provision of the permit shall state that no permit revision shall be required, under any approved economic incentives, marketable permits, emissions trading and other similar programs or processes for changes that are provided for in the permit.

22.108(12) Terms and conditions for reasonably anticipated operating scenarios identified by the source in its application and as approved by the director. Such terms and conditions:

a. Shall require the source, contemporaneously with making a change from one operating scenario to another, to record in a log at the permitted facility a record of the scenario under which it is operating; and

b. Must ensure that the terms and conditions of each such alternative scenario meet all applicable requirements and the requirements of the department's rules.

22.108(13) Terms and conditions, if the permit applicant requests them, for the trading of emissions increases and decreases in the permitted facility, to the extent that the applicable requirements provide for trading such increases and decreases without a case-by-case approval of each emissions trade. Such terms and conditions:

a. Shall include all terms required under subrules 22.108(1) to 22.108(13) and subrule 22.108(15) to determine compliance;

b. Must meet all applicable requirements of the Act and regulations promulgated thereunder and all requirements of this chapter; and

c. May extend the permit shield described in subrule 22.108(18) to all terms and conditions that allow such increases and decreases in emissions.

22.108(14) Federally enforceable requirements.

a. All terms and conditions in a Title V permit, including any provisions designed to limit a source's potential to emit, are enforceable by the administrator and citizens under the Act.

b. Notwithstanding paragraph "a" of this subrule, the director shall specifically designate as not being federally enforceable under the Act any terms and conditions included in the permit that are not required under the Act or under any of its applicable requirements. Terms and conditions so designated are not subject to the requirements of 40 CFR 70.7 or 70.8 (as amended through July 21, 1992).

22.108(15) Compliance requirements. All Title V permits shall contain the following elements with respect to compliance:

a. Consistent with the provisions of subrules 22.108(3) to 22.108(5), compliance certification, testing, monitoring, reporting, and record-keeping requirements sufficient to ensure compliance with the terms and conditions of the permit. Any documents, including reports, required by a permit shall contain a certification by a responsible official that meets the requirements of subrule 22.107(4).

b. Inspection and entry provisions which require that, upon presentation of proper credentials, the permittee shall allow the director or the director's authorized representative to:

(1) Enter upon the permittee's premises where a Title V source is located or emissions-related activity is conducted, or where records must be kept under the conditions of the permit;

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(3) Inspect, at reasonable times, any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit; and

(4) Sample or monitor, at reasonable times, substances or parameters for the purpose of ensuring compliance with the permit or other applicable requirements.

c. A schedule of compliance consistent with subparagraphs 22.105(2) "h" and "j" and subrule 22.105(3).

d. Progress reports, consistent with an applicable schedule of compliance and with the provisions of paragraphs 22.105(2) "h" and "j," to be submitted at least every six months, or more frequently if

specified in the applicable requirement or by the department in the permit. Such progress reports shall contain the following:

(1) Dates for achieving the activities, milestones or compliance required in the schedule of compliance, and dates when such activities, milestones or compliance were achieved; and

(2) An explanation of why any dates in the schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

e. Requirements for compliance certification with terms and conditions contained in the permit, including emission limitations, standards, or work practices. Permits shall include each of the following:

(1) The frequency of submissions of compliance certifications, which shall not be less than annually.

(2) The means to monitor the compliance of the source with its emissions limitations, standards, and work practices, in accordance with the provisions of all applicable department rules.

(3) A requirement that the compliance certification include: the identification of each term or condition of the permit that is the basis of the certification; the compliance status; whether compliance was continuous or intermittent; the method(s) used for determining the compliance status of the source, currently and over the reporting period consistent with all applicable department rules; and other facts as the director may require to determine the compliance status of the source.

(4) A requirement that all compliance certifications be submitted to the administrator and the director.

f. Such additional provisions as the director may require.

g. Such additional provisions as may be specified pursuant to Sections 114(a)(3) and 504(b) of the Act.

h. If there is a federal implementation plan applicable to the source, a provision that compliance with the federal implementation plan is required.

22.108(16) Emergency provisions.

a. For the purposes of a Title V permit, an “emergency” means any situation arising from sudden and reasonably unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by improperly designed equipment, lack of preventive maintenance, careless or improper operation, or operator error.

b. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emission limitations if the conditions of paragraph 22.108(16) “*c*” are met.

c. Requirements for affirmative defense. The affirmative defense of emergency shall be demonstrated by the source through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) An emergency occurred and that the permittee can identify the cause(s) of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of the emergency the permittee took all reasonable steps to minimize levels of emissions that exceeded the emissions standards or other requirements of the permit; and

(4) The permittee submitted notice of the emergency to the director by certified mail within two working days of the time when emission limitations were exceeded due to the emergency. This notice fulfills the requirement of paragraph 22.108(5) “*b*.” This notice must contain a description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.

d. In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof.

e. This provision is in addition to any emergency or upset provision contained in any applicable requirement.

22.108(17) Permit reopenings.

a. A Title V permit issued to a major source shall require that revisions be made to incorporate applicable standards and regulations adopted by the administrator pursuant to the Act, provided that:

(1) The reopening and revision on this ground is not required if the permit has a remaining term of less than three years;

(2) The reopening and revision on this ground is not required if the effective date of the requirement is later than the date on which the permit is due to expire, unless the original permit or any of its terms and conditions have been extended pursuant to 40 CFR 70.4(b)(10)(i) or (ii) as amended through October 6, 2009; or

(3) The additional applicable requirements are implemented in a general permit that is applicable to the source and the source receives approval for coverage under that general permit.

b. The revisions shall be made as expeditiously as practicable, but not later than 18 months after the promulgation of such standards and regulations. Any permit revision required pursuant to this subrule shall be treated as a permit renewal.

22.108(18) Permit shield.

a. The director may expressly include in a Title V permit a provision stating that compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance, provided that:

(1) Such applicable requirements are included and are specifically identified in the permit; or

(2) The director, in acting on the permit application or revision, determines in writing that other requirements specifically identified are not applicable to the source, and the permit includes the determination or a concise summary thereof.

b. A Title V permit that does not expressly state that a permit shield exists shall be presumed not to provide such a shield.

c. A permit shield shall not alter or affect the following:

(1) The provisions of Section 303 of the Act (emergency orders), including the authority of the administrator under that section;

(2) The liability of an owner or operator of a source for any violation of applicable requirements prior to or at the time of permit issuance;

(3) The applicable requirements of the acid rain program, consistent with Section 408(a) of the Act;

(4) The ability of the department or the administrator to obtain information from the facility pursuant to Section 114 of the Act.

22.108(19) Emission trades. For emission trades at facilities solely for the purpose of complying with a federally enforceable emissions cap that is established in the permit independent of otherwise applicable requirements, permit applications under this provision are required to include proposed replicable procedures and proposed permit terms that ensure the emission trades are quantifiable and enforceable.

[ARC 0330C, IAB 9/19/12, effective 10/24/12; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17]

567—22.109(455B) General permits.

22.109(1) Applicability. The director may issue a general permit for multiple sources that contain a number of operations and processes which emit pollutants with similar characteristics and that have substantially similar requirements regarding emissions, operations, monitoring and record keeping. General permits shall not be issued to Title IV affected sources except as provided in regulations promulgated by the administrator under Title IV of the Act.

22.109(2) Issuance of general permits. General permits may be issued by the director and codified in this chapter following notice and opportunity for public participation consistent with the procedures contained in subrule 22.107(6). Public participation shall be provided for a new general permit, for any revision of an existing general permit, and for renewal of an existing general permit. Permit review by the administrator and affected states shall be provided consistent with subrule 22.107(7). Each general permit shall identify criteria by which sources may qualify to operate under the general permit and shall comply with all requirements applicable to other Title V permits.

22.109(3) Applications. Any source that would qualify for a general permit must apply for either (a) coverage under the terms of the general permit or (b) an individual Title V permit. Applications for

authority to operate under the terms of a general permit shall be made on the “General Permit Application Form” and shall specify the general permit concerned by citing the subrule containing that general permit. These applications may deviate from the Title V individual permit application but shall include all information necessary to determine qualification for, and to ensure compliance with, the general permit. If a source is later determined not to qualify for the terms and conditions of the general permit, then the source shall be subject to enforcement action for operation without a Title V operating permit.

22.109(4) *General permit content.* A general permit shall include all of the following:

- a. The terms and conditions required for all sources authorized to operate under the permit;
- b. Emission limitations and standards, including those operational requirements and limitations that ensure compliance with all applicable requirements at the time of the permit issuance;
- c. A compliance plan;
- d. Monitoring, record keeping, and reporting requirements to ensure compliance with the terms and conditions of the general permit. These requirements shall ensure the use of consistent terms, test methods, units, averaging periods, and other statistical conventions consistent with the applicable emissions limitations, standards, and other requirements contained in the general permit;
- e. The requirement to submit at least every six months the results of any required monitoring;
- f. References to the authority for the term or condition;
- g. A provision specifying permit duration as a fixed term not to exceed five years;
- h. A severability clause provision pursuant to subrule 22.108(8);
- i. A provision for payment of fees pursuant to subrule 22.108(10);
- j. A provision for emissions trading pursuant to subrules 22.108(11) and 22.108(13);
- k. Other provisions pursuant to subrule 22.108(9);
- l. Statement that the Title V permit is to be kept at the site of the source as well as at the corporate offices; and
- m. The process for individual sources to apply for coverage under the general permit.

22.109(5) *Action on general permit application.*

- a. Once the director has issued a general permit, any source which is a member of the class of sources covered by the general permit may apply to the director for authority to operate under the general permit.
- b. Review of a general permit application. The director shall grant the conditions and terms of a general permit to all sources that apply and qualify under the identified criteria.
- c. The director may grant a source’s request for authorization to operate under a general permit without repeating the public participation procedures followed in subrule 22.109(2). However, such a grant shall not be a final permit action for purposes of judicial review.

22.109(6) *General permit renewal.* The director shall review and may renew general permits every five years. A source’s authorization to operate under a general permit shall expire when the general permit expires regardless of when the authorization began during the five-year period.

22.109(7) *Relationship to individual permits.* Any source covered by a general permit may request to be excluded from coverage by applying for an individual Title V permit. Coverage under the general permit shall terminate on the date the individual Title V permit is issued.

22.109(8) *Permit shield for general permit.* Each general permit issued under this chapter shall specifically identify all federal, state, and local air pollution control requirements applicable to the source at the time the permit is issued. The permit shall state that compliance with the conditions of the permit shall be deemed compliance with any applicable requirements as of the date of permit issuance. Any permit under this chapter that does not expressly state that a permit shield exists shall be presumed not to provide such a shield. Notwithstanding the above provisions, the source shall be subject to enforcement action for operation without a permit if the source is later determined not to qualify for the conditions and terms of the general permit.

22.109(9) *Revocations of authority to operate.*

- a. The director may require any source or a class of sources authorized to operate under a general permit to individually apply for and obtain a Title V permit at any time if:
 - (1) The source is not in compliance with the terms and conditions of the general permit;

(2) The director has determined that the emissions from the source or class of sources is contributing significantly to ambient air quality standard violations and that these emissions are not adequately addressed by the terms and conditions of the general permit; or

(3) The director has information which indicates that the cumulative effects on human health and the environment from the sources covered under the general permit are unacceptable.

b. The director shall provide written notice to all sources operating under that general permit of the proposed revocation of that general permit. Such notice shall include an explanation of the basis for the proposed action.

567—22.110(455B) Changes allowed without a Title V permit revision (off-permit revisions).

22.110(1) A source with a Title V permit may make Section 502(b)(10) changes to the permitted installation/facility without a Title V permit revision if:

a. The changes are not major modifications under any provision of any program required by Section 110 of the Act, modifications under Section 111 of the Act, modifications under Section 112 of the Act, or major modifications of this chapter;

b. The changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions);

c. The changes are not modifications under any provision of Title I of the Act and the changes do not exceed the emissions allowable under the permit (whether expressed therein as a rate of emissions or in terms of total emissions);

d. The changes are not subject to any requirement under Title IV of the Act (revisions affecting Title IV permitting are addressed in rules 567—22.140(455B) through 567—22.144(455B));

e. The changes comply with all applicable requirements; and

f. For each such change, the permitted source provides to the department and the administrator by certified mail, at least 30 days in advance of the proposed change, a written notification, including the following, which shall be attached to the permit by the source, the department, and the administrator:

(1) A brief description of the change within the permitted facility,

(2) The date on which the change will occur,

(3) Any change in emission as a result of the change,

(4) The pollutants emitted subject to the emissions trade,

(5) If the emissions trading provisions of the state implementation plan are invoked, then the Title V permit requirements with which the source shall comply; a description of how the emission increases and decreases will comply with the terms and conditions of the Title V permit;

(6) A description of the trading of emissions increases and decreases for the purpose of complying with a federally enforceable emissions cap as specified in and in compliance with the Title V permit; and

(7) Any permit term or condition no longer applicable as a result of the change.

22.110(2) Such changes do not include changes that would violate applicable requirements or contravene federally enforceable permit terms and conditions that are monitoring (including test methods), record keeping, reporting, or compliance certification requirements.

22.110(3) Notwithstanding any other part of this rule, the director may, upon review of a notice, require a stationary source to apply for a Title V permit if the change does not meet the requirements of subrule 22.110(1).

22.110(4) The permit shield provided in subrule 22.108(18) shall not apply to any change made pursuant to this rule. Compliance with the permit requirements that the source will meet using the emissions trade shall be determined according to requirements of the state implementation plan authorizing the emissions trade.

567—22.111(455B) Administrative amendments to Title V permits.

22.111(1) An administrative permit amendment is a permit revision that does any of the following:

a. Corrects typographical errors;

b. Identifies a change in the name, address, or telephone number of any person identified in the permit, or provides a similar minor administrative change at the source;

- c.* Requires more frequent monitoring or reporting by the permittee; or
- d.* Allows for a change in ownership or operational control of a source where the director determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittee has been submitted to the director.

22.111(2) Administrative permit amendments to portions of permits containing provisions pursuant to Title IV of the Act shall be governed by regulations promulgated by the administrator under Title IV of the Act.

22.111(3) The director shall take no more than 60 days from receipt of a request for an administrative permit amendment to take final action on such request, and may incorporate such changes without providing notice to the public or affected states provided that the director designates any such permit revisions as having been made pursuant to this rule.

22.111(4) The director shall submit to the administrator a copy of each Title V permit revised under this rule.

22.111(5) The source may implement the changes addressed in the request for an administrative amendment immediately upon submittal of the request.

567—22.112(455B) Minor Title V permit modifications.

22.112(1) Minor Title V permit modification procedures may be used only for those permit modifications that satisfy all of the following:

- a.* Do not violate any applicable requirement;
- b.* Do not involve significant changes to existing monitoring, reporting, or record-keeping requirements in the Title V permit;
- c.* Do not require or change a case-by-case determination of an emission limitation or other standard, or an increment analysis;
- d.* Do not seek to establish or change a permit term or condition for which there is no corresponding underlying applicable requirement and that the source has assumed in order to avoid an applicable requirement to which the source would otherwise be subject. Such terms and conditions include any federally enforceable emissions caps which the source would assume to avoid classification as a modification under any provision of Title I of the Act; and an alternative emissions limit approved pursuant to regulations promulgated under Section 112(i)(5) of the Act;
- e.* Are not modifications under any provision of Title I of the Act; and
- f.* Are not required to be processed as a significant modification under rule 567—22.113(455B).

22.112(2) An application for minor permit revision shall be on the minor Title V modification application form and shall include at least the following:

- a.* A description of the change, the emissions resulting from the change, and any new applicable requirements that will apply if the change occurs;
- b.* The source's suggested draft permit;
- c.* Certification by a responsible official, pursuant to subrule 22.107(4), that the proposed modification meets the criteria for use of minor permit modification procedures and a request that such procedures be used; and
- d.* Completed forms to enable the department to notify the administrator and affected states as required by subrule 22.107(7).

22.112(3) The department shall notify the administrator and affected states within five working days of receipt of a complete permit modification application. Notification shall be in accordance with the provisions of subrule 22.107(7). The department shall promptly send to the administrator any notification required by subrule 22.107(7).

22.112(4) The director shall not issue a final Title V permit modification until after the administrator's 45-day review period or until the administrator has notified the director that the administrator will not object to issuance of the Title V permit modification, whichever is first. Within 90 days of the director's receipt of an application under the minor permit modification procedures, or

15 days after the end of the administrator's 45-day review period provided for in subrule 22.107(7), whichever is later, the director shall:

- a. Issue the permit modification as proposed;
- b. Deny the permit modification application;
- c. Determine that the requested permit modification does not meet the minor permit modification criteria and should be reviewed under the significant modification procedures; or
- d. Revise the draft permit modification and transmit to the administrator the proposed permit modification, as required by subrule 22.107(7).

22.112(5) Source's ability to make change. The source may make the change proposed in its minor permit modification application immediately after it files the application. After the source makes the change allowed by the preceding sentence, and until the director takes any of the actions specified in paragraphs 22.112(4) "a" to "c," the source must comply with both the applicable requirements governing the change and the proposed permit terms and conditions. During this time, the source need not comply with the existing permit terms and conditions it seeks to modify. However, if the source fails to comply with its proposed permit terms and conditions during this time period, the existing permit terms and conditions it seeks to modify may be enforced against it.

22.112(6) Permit shield. The permit shield under subrule 22.108(18) shall not extend to minor Title V permit revisions.

567—22.113(455B) Significant Title V permit modifications.

22.113(1) Significant Title V modification procedures shall be used for applications requesting Title V permit modifications that do not qualify as minor Title V modifications or as administrative amendments. These include, but are not limited to, all significant changes in monitoring permit terms, every relaxation of reporting or record-keeping permit terms, and any change in the method of measuring compliance with existing requirements.

22.113(2) Significant Title V permit modifications shall meet all requirements of this chapter, including those for applications, public participation, review by affected states, and review by the administrator, as those requirements that apply to Title V permit issuance and renewal.

22.113(3) Unless the director determines otherwise, review of significant Title V permit modification applications shall be completed within nine months of receipt of a complete application.

22.113(4) For a change that is subject to the requirements for a significant permit modification (see rule 567—22.113(455B)), the permittee shall submit to the department an application for a significant permit modification not later than three months after commencing operation of the changed source unless the existing Title V permit would prohibit such construction or change in operation, in which event the operation of the changed source may not commence until the department revises the permit.

567—22.114(455B) Title V permit reopenings.

22.114(1) Each issued Title V permit shall include provisions specifying the conditions under which the permit may be reopened and revised prior to the expiration of the permit. A permit shall be reopened and revised under any of the following circumstances:

a. The department receives notice that the administrator has granted a petition for disapproval of a permit pursuant to 40 CFR 70.8(d) as amended to July 21, 1992, provided that the reopening may be stayed pending judicial review of that determination;

b. The department or the administrator determines that the Title V permit contains a material mistake or that inaccurate statements were made in establishing the emissions standards or other terms or conditions of the Title V permit;

c. Additional applicable requirements under the Act become applicable to a Title V source, provided that the reopening on this ground is not required if the permit has a remaining term of less than three years, the effective date of the requirement is later than the date on which the permit is due to expire, or the additional applicable requirements are implemented in a general permit that is applicable to the source and the source receives approval for coverage under that general permit. Such a reopening shall be complete not later than 18 months after promulgation of the applicable requirement.

d. Additional requirements, including excess emissions requirements, become applicable to a Title IV affected source under the acid rain program. Upon approval by the administrator, excess emissions offset plans shall be deemed to be incorporated into the permit.

e. The department or the administrator determines that the permit must be revised or revoked to ensure compliance by the source with the applicable requirements.

22.114(2) Proceedings to reopen and reissue a Title V permit shall follow the procedures applicable to initial permit issuance and shall affect only those parts of the permit for which cause to reopen exists.

22.114(3) A notice of intent shall be provided to the Title V source at least 30 days in advance of the date the permit is to be reopened, except that the director may provide a shorter time period in the case of an emergency.

22.114(4) Within 90 days of receipt of a notice from the administrator that cause exists to reopen a permit, the director shall forward to the administrator and the source a proposed determination of termination, modification, revocation, or reissuance of the permit, as appropriate.

567—22.115(455B) Suspension, termination, and revocation of Title V permits.

22.115(1) Permits may be terminated, modified, revoked, or reissued for cause. The following examples shall be considered cause for the suspension, modification, revocation, or reissuance of a Title V permit:

a. The director has reasonable cause to believe that the permit was obtained by fraud or misrepresentation.

b. The person applying for the permit failed to disclose a material fact required by the permit application form or the rules applicable to the permit, of which the applicant had or should have had knowledge at the time the application was submitted.

c. The terms and conditions of the permit have been or are being violated.

d. The permittee has failed to pay the Title V permit fees.

e. The permittee has failed to pay an administrative, civil or criminal penalty imposed for violations of the permit.

22.115(2) If the director suspends, terminates or revokes a Title V permit under this rule, the notice of such action shall be served on the applicant or permittee by certified mail, return receipt requested. The notice shall include a statement detailing the grounds for the action sought, and the proceeding shall in all other respects comply with the requirements of rule 561—7.16(17A,455A).

567—22.116(455B) Title V permit renewals.

22.116(1) An application for Title V permit renewal shall be subject to the same procedural requirements that apply to initial permit issuance, including those for public participation and review by the administrator and affected states.

22.116(2) Except as provided in rule 567—22.104(455B), permit expiration terminates a source's right to operate unless a timely and complete application for renewal has been submitted in accordance with rule 567—22.105(455B).

567—22.117 to 22.119 Reserved.

567—22.120(455B) Acid rain program—definitions. The terms used in rules 567—22.120(455B) through 567—22.147(455B) shall have the meanings set forth in Title IV of the Clean Air Act, 42 U.S.C. 7401, et seq., as amended through November 15, 1990, and in this rule. The definitions set forth in 40 CFR Part 72 as amended through March 28, 2011, and 40 CFR Part 76 as amended through October 15, 1999, are adopted by reference.

“40 CFR Part 72,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 72, or the cited provision therein, as amended through March 28, 2011.

“40 CFR Part 73,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 73, or the cited provision therein, as amended through April 28, 2006.

“40 CFR Part 74,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 74, or the cited provision therein, as amended through April 28, 2006.

“40 CFR Part 75,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 75, or the cited provision therein, as amended through August 30, 2016.

“40 CFR Part 76,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 76, or the cited provision therein, as amended through October 15, 1999.

“40 CFR Part 77,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 77, or the cited provision therein, as amended through May 12, 2005.

“40 CFR Part 78,” or any cited provision therein, shall mean 40 Code of Federal Regulations Part 78, or the cited provision therein, as amended through August 8, 2011.

“Acid rain permit” means the legally binding written document, or portion of such document, issued by the department (following an opportunity for appeal as set forth in 561—Chapter 7, as adopted by reference at 567—Chapter 7), including any permit revisions, specifying the acid rain program requirements applicable to an affected source, to each affected unit at an affected source, and to the owner and operators and the designated representative of the affected source or the affected unit.

“Department” means the department of natural resources and is the state acid rain permitting authority.

“Draft acid rain permit” means the version of the acid rain permit, or the acid rain portion of a Title V operating permit, that the department offers for public comment.

“Electronic format,” “electronic submittal,” and “electronic submittal format” mean a software, Internet-based, or other electronic means specified by the department for submitting information or fees to the department related to, but not limited to, applications, certifications, determination requests, emissions inventories, forms, notifications, payments, permit applications and registrations. References to these information submittal methods in rules 567—22.120(455B) through 567—22.146(455B) may, as specified by the department, include electronic submittal.

“Permit revision” means a permit modification, fast-track modification, administrative permit amendment, or automatic permit amendment, as provided in rules 567—22.140(455B) through 567—22.144(455B).

“Proposed acid rain permit” means the version of the acid rain permit that the department submits to the Administrator after the public comment period, but prior to completion of the EPA permit review under 40 CFR 70.8(c) as amended through July 21, 1992.

“Title V operating permit” means a permit issued under rules 567—22.100(455B) through 567—22.116(455B) implementing Title V of the Act.

“Ton” or “tonnage” means any short ton (i.e., 2,000 pounds). For purposes of determining compliance with the acid rain emissions limitations and reduction requirements, total tons for a year shall be calculated as the sum of all recorded hourly emissions (or the tonnage equivalent of the recorded hourly emissions) in accordance with rule 567—25.2(455B), with any remaining fraction of a ton equal to or greater than 0.50 ton deemed to equal one ton and any fraction of a ton less than 0.50 ton deemed not equal to a ton.

[ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—22.121(455B) Measurements, abbreviations, and acronyms. Measurements, abbreviations, and acronyms used in rules 567—22.120(455B) to 567—22.147(455B) are defined as follows:

“ASTM” means American Society for Testing and Materials.

“Btu” means British thermal unit.

“CFR” means Code of Federal Regulations.

“DOE” means Department of Energy.

“EPA” means Environmental Protection Agency.

“mmBtu” means million Btu.

“MWe” means megawatt electrical.

“SO₂” means sulfur dioxide.

567—22.122(455B) Applicability.

22.122(1) Each of the following units shall be an affected unit, and any source that includes such a unit shall be an affected source, subject to the requirements of the acid rain program:

- a.* A unit listed in Table 1 of 40 CFR 73.10(a).
- b.* An existing unit that is identified in Table 2 or 3 of 40 CFR 73.10, and any other existing utility unit, except a unit under subrule 22.122(2).
- c.* A utility unit, except a unit under subrule 22.122(2), that:
 - (1) Is a new unit;
 - (2) Did not serve a generator with a nameplate capacity greater than 25 MWe on November 15, 1990, but serves such a generator after November 15, 1990;
 - (3) Was a simple combustion turbine on November 15, 1990, but adds or uses auxiliary firing after November 15, 1990;
 - (4) Was an exempt cogeneration facility under paragraph 22.122(2)“*d*” but during any three-calendar-year period after November 15, 1990, sold, to a utility power distribution system, an annual average of more than one-third of its potential electrical output capacity and more than 219,000 MWe-hrs electric output, on a gross basis;
 - (5) Was an exempt qualifying facility under paragraph 22.122(2)“*e*” but, at any time after the later of November 15, 1990, or the date the facility commences commercial operation, fails to meet the definition of qualifying facility;
 - (6) Was an exempt independent power production facility under paragraph 22.122(2)“*f*” but, at any time after the later of November 15, 1990, or the date the facility commences commercial operation, fails to meet the definition of independent power production facility; or
 - (7) Was an exempt solid waste incinerator under paragraph 22.122(2)“*g*” but during any three-calendar-year period after November 15, 1990, consumes 20 percent or more (on a Btu basis) fossil fuel.
- (8) Is a coal-fired substitution unit that is designated in a substitution plan that was not approved and not active as of January 1, 1995, or is a coal-fired compensating unit.

22.122(2) The following types of units are not affected units subject to the requirements of the acid rain program:

- a.* A simple combustion turbine that commenced operation before November 15, 1990.
- b.* Any unit that commenced commercial operation before November 15, 1990, and that did not, as of November 15, 1990, and does not currently, serve a generator with a nameplate capacity of greater than 25 MWe.
- c.* Any unit that, during 1985, did not serve a generator that produced electricity for sale and that did not, as of November 15, 1990, and does not currently, serve a generator that produces electricity for sale.
- d.* A cogeneration facility which:
 - (1) For a unit that commenced construction on or prior to November 15, 1990, was constructed for the purpose of supplying equal to or less than one-third its potential electrical output capacity or equal to or less than 219,000 MWe-hrs actual electric output on an annual basis to any utility power distribution system for sale (on a gross basis). If the purpose of construction is not known, it will be presumed to be consistent with the actual operation from 1985 through 1987. However, if in any three-calendar-year period after November 15, 1990, such unit sells to a utility power distribution system an annual average of more than one-third of its potential electrical output capacity and more than 219,000 MWe-hrs actual electric output (on a gross basis), that unit shall be an affected unit, subject to the requirements of the acid rain program; or
 - (2) For units that commenced construction after November 15, 1990, supplies equal to or less than one-third its potential electrical output capacity or equal to or less than 219,000 MWe-hrs actual electric output on an annual basis to any utility power distribution system for sale (on a gross basis). However, if in any three-calendar-year period after November 15, 1990, such unit sells to a utility power distribution system an annual average of more than one-third of its potential electrical output capacity and more than

219,000 MWe-hrs actual electric output (on a gross basis), that unit shall be an affected unit, subject to the requirements of the acid rain program.

e. A qualifying facility that:

(1) Has, as of November 15, 1990, one or more qualifying power purchase commitments to sell at least 15 percent of its total planned net output capacity; and

(2) Consists of one or more units designated by the owner or operator with total installed net output capacity not exceeding 130 percent of the total planned net output capacity. If the emissions rates of the units are not the same, the administrator may exercise discretion to designate which units are exempt.

f. An independent power production facility that:

(1) Has, as of November 15, 1990, one or more qualifying power purchase commitments to sell at least 15 percent of its total planned net output capacity; and

(2) Consists of one or more units designated by the owner or operator with total installed net output capacity not exceeding 130 percent of its total planned net output capacity. If the emissions rates of the units are not the same, the administrator may exercise discretion to designate which units are exempt.

g. A solid waste incinerator, if more than 80 percent (on a Btu basis) of the annual fuel consumed at such incinerator is other than fossil fuels. For a solid waste incinerator which began operation before January 1, 1985, the average annual fuel consumption of nonfossil fuels for calendar years 1985 through 1987 must be greater than 80 percent for such an incinerator to be exempt. For a solid waste incinerator which began operation after January 1, 1985, the average annual fuel consumption of nonfossil fuels for the first three years of operation must be greater than 80 percent for such an incinerator to be exempt. If, during any three-calendar-year period after November 15, 1990, such incinerator consumes 20 percent or more (on a Btu basis) fossil fuel, such incinerator will be an affected source under the acid rain program.

h. A nonutility unit.

22.122(3) A certifying official of any unit may petition the administrator for a determination of applicability under 40 CFR 72.6(c). The administrator's determination of applicability shall be binding upon the department, unless the petition is found to have contained significant errors or omissions.

567—22.123(455B) Acid rain exemptions.

22.123(1) *New unit exemption.* The new unit exemption, as specified in 40 CFR §72.7, except for 40 CFR §72.7(c)(1)(i), is adopted by reference. This exemption applies to new utility units.

22.123(2) *Retired unit exemption.* The retired unit exemption, as specified in 40 CFR §72.8, is adopted by reference. This exemption applies to any affected unit that is permanently retired.

22.123(3) *Industrial utility-unit exemption.* The industrial utility-unit exemption, as specified in 40 CFR §72.14, is adopted by reference. This exemption applies to any noncogeneration utility unit.

567—22.124(455B) Retired units exemption. Rescinded IAB 9/9/98, effective 10/14/98.

567—22.125(455B) Standard requirements.

22.125(1) *Permit requirements.*

a. The designated representative of each affected source and each affected unit at the source shall:

(1) Submit a complete acid rain permit application under this chapter in accordance with the deadlines specified in rule 567—22.128(455B);

(2) Submit in a timely manner any supplemental information that the department determines is necessary in order to review an acid rain permit application and issue or deny an acid rain permit.

b. The owners and operators of each affected source and each affected unit at the source shall:

(1) Operate the unit in compliance with a complete acid rain permit application or a superseding acid rain permit issued by the department; and

(2) Have an acid rain permit.

22.125(2) *Monitoring requirements.*

a. The owners and operators and, to the extent applicable, designated representative of each affected source and each affected unit at the source shall comply with the monitoring requirements as

provided in rule 567—25.2(455B) and Section 407 of the Act and regulations implementing Section 407 of the Act.

b. The emissions measurements recorded and reported in accordance with rule 567—25.2(455B) and Section 407 of the Act and regulations implementing Section 407 of the Act shall be used to determine compliance by the unit with the acid rain emissions limitations and emissions reduction requirements for sulfur dioxide and nitrogen oxides under the acid rain program.

c. The requirements of rule 567—25.2(455B) and regulations implementing Section 407 of the Act shall not affect the responsibility of the owners and operators to monitor emissions of other pollutants or other emissions characteristics at the unit under other applicable requirements of the Act and other provisions of the operating permit for the source.

22.125(3) Sulfur dioxide requirements.

a. The owners and operators of each source and each affected unit at the source shall:

(1) Hold allowances, as of the allowance transfer deadline, in the unit's compliance subaccount (after deductions under 40 CFR 73.34(c)) not less than the total annual emissions of sulfur dioxide for the previous calendar year from the unit; and

(2) Comply with the applicable acid rain emissions limitation for sulfur dioxide.

b. Each ton of sulfur dioxide emitted in excess of the acid rain emissions limitations for sulfur dioxide shall constitute a separate violation of the Act.

c. An affected unit shall be subject to the requirements under paragraph 22.125(3) "a" as follows: starting January 1, 2000, an affected unit under paragraph 22.122(1) "b"; or starting on the later of January 1, 2000, or the deadline for monitor certification under rule 567—25.2(455B), an affected unit under paragraph 22.122(1) "c."

d. Allowances shall be held in, deducted from, or transferred among allowance tracking system accounts in accordance with the acid rain program.

e. An allowance shall not be deducted, in order to comply with the requirements under paragraph 22.125(3) "a," prior to the calendar year for which the allowance was allocated.

f. An allowance allocated by the administrator under the acid rain program is a limited authorization to emit sulfur dioxide in accordance with the acid rain program. No provision of the acid rain program, the acid rain permit application, the acid rain permit, or the written exemption under rules 567—22.123(455B) and 567—22.124(455B) and no provision of law shall be construed to limit the authority of the United States to terminate or limit such authorization.

g. An allowance allocated by the administrator under the acid rain program does not constitute a property right.

22.125(4) Nitrogen oxides requirements. The owners and operators of the source and each affected unit at the source shall comply with the applicable acid rain emission limitation for nitrogen oxides, as specified in 40 CFR Sections 76.5 and 76.7; 76.6; and 76.8, 76.11, 76.12, and 76.15; or by alternative emission limitations provided for by 40 CFR 76.10, as long as the alternative emission limitation has been petitioned and demonstrated according to 40 CFR 76.14 and approved by the department.

22.125(5) Excess emissions requirements.

a. The designated representative of an affected unit that has excess emissions in any calendar year shall submit a proposed offset plan to the administrator, as required under 40 CFR Part 77, and submit a copy to the department.

b. The owners and operators of an affected unit that has excess emissions in any calendar year shall:

(1) Pay to the administrator without demand the penalty required, and pay to the administrator upon demand the interest on that penalty, as required by 40 CFR Part 77; and

(2) Comply with the terms of an approved offset plan, as required by 40 CFR Part 77.

22.125(6) Record-keeping and reporting requirements.

a. Unless otherwise provided, the owners and operators of the source and each affected unit at the source shall keep on site at the source each of the following documents for a period of five years from the date the document is created. This period may be extended for cause, at any time prior to the end of five years, in writing by the administrator or the department.

(1) The certificate of representation for the designated representative for the source and each affected unit at the source and all documents that demonstrate the truth of the statements in the certificate of representation, in accordance with 40 CFR 72.24; provided that the certificate and documents shall be retained on site at the source beyond such five-year period until such documents are superseded because of the submission of a new certificate of representation changing the designated representative.

(2) All emissions monitoring information, in accordance with rule 567—25.2(455B).

(3) Copies of all reports, compliance certifications, and other submissions and all records made or required under the acid rain program.

(4) Copies of all documents used to complete an acid rain permit application and any other submission under the acid rain program or to demonstrate compliance with the requirements of the acid rain program.

b. The designated representative of an affected source and each affected unit at the source shall submit the reports and compliance certifications required under the acid rain program, including those under rules 567—22.146(455B) and 567—22.147(455B) and rule 567—25.2(455B).

22.125(7) Liability.

a. Any person who knowingly violates any requirement or prohibition of the acid rain program, a complete acid rain permit application, an acid rain permit, or a written exemption under rules 567—22.123(455B) or 567—22.124(455B), including any requirement for the payment of any penalty owed to the United States, shall be subject to enforcement by the administrator pursuant to Section 113(c) of the Act and by the department pursuant to Iowa Code section 455B.146.

b. Any person who knowingly makes a false, material statement in any record, submission, or report under the acid rain program shall be subject to criminal enforcement by the administrator pursuant to Section 113(c) of the Act and 18 U.S.C. 1001 and by the department pursuant to Iowa Code section 455B.146.

c. No permit revision shall excuse any violation of the requirements of the acid rain program that occurs prior to the date that the revision takes effect.

d. Each affected source and each affected unit shall meet the requirements of the acid rain program.

e. Any provision of the acid rain program that applies to an affected source (including a provision applicable to the designated representative of an affected source) shall also apply to the owners and operators of such source and of the affected units at the source.

f. Any provision of the acid rain program that applies to an affected unit (including a provision applicable to the designated representative of an affected unit) shall also apply to the owners and operators of such unit. Except as provided under rule 567—22.132(455B) (Phase II repowering extension plans), Section 407 of the Act and regulations implementing Section 407 of the Act, and except with regard to the requirements applicable to units with a common stack under rule 567—25.2(455B), the owners and operators and the designated representative of one affected unit shall not be liable for any violation by any other affected unit of which they are not owners or operators or the designated representative and that is located at a source of which they are not owners or operators or the designated representative.

g. Each violation of a provision of rules 567—22.120(455B) to 567—22.146(455B) and 40 CFR Parts 72, 73, 75, 76, 77, and 78 and regulations implementing Sections 407 and 410 of the Act by an affected source or affected unit, or by an owner or operator or designated representative of such source or unit, shall be a separate violation of the Act.

22.125(8) Effect on other authorities. No provision of the acid rain program, an acid rain permit application, an acid rain permit, or a written exemption under rule 567—22.123(455B) or 567—22.124(455B) shall be construed as:

a. Except as expressly provided in Title IV of the Act, exempting or excluding the owners and operators and, to the extent applicable, the designated representative of an affected source or affected unit from compliance with any other provision of the Act, including the provisions of Title I of the Act relating to applicable National Ambient Air Quality Standards or State Implementation Plans;

b. Limiting the number of allowances a unit can hold; provided that the number of allowances held by the unit shall not affect the source's obligation to comply with any other provisions of the Act;

- c.* Requiring a change of any kind in any state law regulating electric utility rates and charges, affecting any state law regarding such state rule, or limiting such state rule, including any prudence review requirements under such state law;
- d.* Modifying the Federal Power Act or affecting the authority of the Federal Energy Regulatory Commission under the Federal Power Act; or
- e.* Interfering with or impairing any program for competitive bidding for power supply in a state in which such program is established.

567—22.126(455B) Designated representative—submissions.

22.126(1) The designated representative shall submit a certificate of representation, and any superseding certificate of representation, to the administrator in accordance with Subpart B of 40 CFR Part 72, and, concurrently, shall submit a copy to the department. Whenever the term “designated representative” is used in this rule, the term shall be construed to include the alternate designated representative.

22.126(2) Each submission under the acid rain program shall be submitted, signed, and certified by the designated representative for all sources on behalf of which the submission is made.

22.126(3) In each submission under the acid rain program, the designated representative shall certify by signature:

a. The following statement, which shall be included verbatim in such submission: “I am authorized to make this submission on behalf of the owners and operators of the affected source or affected units for which the submission is made.”

b. The following statement, which shall be included verbatim in such submission: “I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this document and all its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment.”

22.126(4) The department will accept or act on a submission made on behalf of owners or operators of an affected source and an affected unit only if the submission has been made, signed, and certified in accordance with subrules 22.126(2) and 22.126(3).

22.126(5) The designated representative of a source shall serve notice on each owner and operator of the source and of an affected unit at the source:

a. By the date of submission, of any acid rain program submissions by the designated representative;

b. Within ten business days of receipt of a determination, of any written determination by the administrator or the department; and

c. Provided that the submission or determination covers the source or the unit.

22.126(6) The designated representative of a source shall provide each owner and operator of an affected unit at the source a copy of any submission or determination under subrule 22.126(5), unless the owner or operator expressly waives the right to receive such a copy.

567—22.127(455B) Designated representative—objections.

22.127(1) Except as provided in 40 CFR 72.23, no objection or other communication submitted to the administrator or the department concerning the authorization, or any submission, action or inaction, of the designated representative shall affect any submission, action, or inaction of the designated representative, or the finality of any decision by the department, under the acid rain program. In the event of such communication, the department is not required to stay any submission or the effect of any action or inaction under the acid rain program.

22.127(2) The department will not adjudicate any private legal dispute concerning the authorization or any submission, action, or inaction of any designated representative, including private legal disputes concerning the proceeds of allowance transfers.

567—22.128(455B) Acid rain applications—requirement to apply.

22.128(1) *Duty to apply.* The designated representative of any source with an affected unit shall submit a complete acid rain permit application by the applicable deadline in subrules 22.128(2) and 22.128(3), and the owners and operators of such source and any affected unit at the source shall not operate the source or unit without a permit that states its acid rain program requirements.

22.128(2) *Deadlines.*

a. For any source with an existing unit described under paragraph 22.122(1) “*b*,” the designated representative shall submit a complete acid rain permit application governing such unit to the department on or before January 1, 1996.

b. For any source with a new unit described under subparagraph 22.122(1) “*c*”(1), the designated representative shall submit a complete acid rain permit application governing such unit to the department at least 24 months before the later of January 1, 2000, or the date on which the unit commences operation.

c. For any source with a unit described under subparagraph 22.122(1) “*c*”(2), the designated representative shall submit a complete acid rain permit application governing such unit to the department at least 24 months before the later of January 1, 2000, or the date on which the unit begins to serve a generator with a nameplate capacity greater than 25 MWe.

d. For any source with a unit described under subparagraph 22.122(1) “*c*”(3), the designated representative shall submit a complete acid rain permit application governing such unit to the department at least 24 months before the later of January 1, 2000, or the date on which the auxiliary firing commences operation.

e. For any source with a unit described under subparagraph 22.122(1) “*c*”(4), the designated representative shall submit a complete acid rain permit application governing such unit to the department before the later of January 1, 1998, or March 1 of the year following the three-calendar-year period in which the unit sold to a utility power distribution system an annual average of more than one-third of its potential electrical output capacity and more than 219,000 MWe-hrs actual electric output (on a gross basis).

f. For any source with a unit described under subparagraph 22.122(1) “*c*”(5), the designated representative shall submit a complete acid rain permit application governing such unit to the department before the later of January 1, 1998, or March 1 of the year following the calendar year in which the facility fails to meet the definition of qualifying facility.

g. For any source with a unit described under subparagraph 22.122(1) “*c*”(6), the designated representative shall submit a complete acid rain permit application governing such unit to the department before the later of January 1, 1998, or March 1 of the year following the calendar year in which the facility fails to meet the definition of an independent power production facility.

h. For any source with a unit described under subparagraph 22.122(1) “*c*”(7), the designated representative shall submit a complete acid rain permit application governing such unit to the department before the later of January 1, 1998, or March 1 of the year following the three-calendar-year period in which the incinerator consumed 20 percent or more fossil fuel (on a Btu basis).

i. For a Phase II unit with a Group 1 or a Group 2 boiler, the designated representative shall submit a complete permit application and compliance plan for NO_x emissions to the department no later than January 1, 1998.

22.128(3) *Duty to reapply.* The designated representative shall submit a complete acid rain permit application for each source with an affected unit at least six months prior to the expiration of an existing acid rain permit governing the unit.

22.128(4) *Submission of copies.* One copy of all permit applications shall be presented or mailed to the air quality bureau of the department of natural resources. Alternatively, the designated representative may, as specified by the department, submit the application through electronic submittal.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—22.129(455B) Information requirements for acid rain permit applications. A complete acid rain permit application shall be submitted on a form approved by the department, which includes the following elements:

22.129(1) Identification of the affected source for which the permit application is submitted;

22.129(2) Identification of each affected unit at the source for which the permit application is submitted;

22.129(3) A complete compliance plan for each unit, in accordance with rules 567—22.131(455B) and 567—22.132(455B);

22.129(4) The standard requirements under rule 567—22.125(455B); and

22.129(5) If the unit is a new unit, the date that the unit has commenced or will commence operation and the deadline for monitor certification.

567—22.130(455B) Acid rain permit application shield and binding effect of permit application.

22.130(1) Once a designated representative submits a timely and complete acid rain permit application, the owners and operators of the affected source and the affected units covered by the permit application shall be deemed in compliance with the requirement to have an acid rain permit under paragraph 22.125(1) “b” and subrule 22.128(1); provided that any delay in issuing an acid rain permit is not caused by the failure of the designated representative to submit in a complete and timely fashion supplemental information, as required by the department, necessary to issue a permit.

22.130(2) Prior to the date on which an acid rain permit is issued as a final agency action subject to judicial review, an affected unit governed by and operated in accordance with the terms and requirements of a timely and complete acid rain permit application shall be deemed to be operating in compliance with the acid rain program.

22.130(3) A complete acid rain permit application shall be binding on the owners and operators and the designated representative of the affected source and the affected units covered by the permit application and shall be enforceable as an acid rain permit from the date of submission of the permit application until the issuance or denial of such permit as a final agency action subject to judicial review.

567—22.131(455B) Acid rain compliance plan and compliance options—general.

22.131(1) For each affected unit included in an acid rain permit application, a complete compliance plan shall include:

a. For sulfur dioxide emissions, a certification that, as of the allowance transfer deadline, the designated representative will hold allowances in the unit’s compliance subaccount (after deductions under 40 CFR 73.34(c)) not less than the total annual emissions of sulfur dioxide from the unit. The compliance plan may also specify, in accordance with rule 567—22.131(455B), one or more of the acid rain compliance options.

b. For nitrogen oxides emissions, a certification that the unit will comply with the applicable limitation established by subrule 22.125(4) or shall specify one or more acid rain compliance options, in accordance with Section 407 of the Act, and 40 CFR Section 76.9.

22.131(2) The compliance plan may include a multiunit compliance option under rule 567—22.132(455B) or Section 407 of the Act or regulations implementing Section 407.

a. A plan for a compliance option that includes units at more than one affected source shall be complete only if:

(1) Such plan is signed and certified by the designated representative for each source with an affected unit governed by such plan; and

(2) A complete permit application is submitted covering each unit governed by such plan.

b. The department’s approval of a plan under paragraph 22.131(2) “a” that includes units in more than one state shall be final only after every permitting authority with jurisdiction over any such unit has approved the plan with the same modifications or conditions, if any.

22.131(3) Conditional approval. In the compliance plan, the designated representative of an affected unit may propose, in accordance with rules 567—22.131(455B) and 567—22.132(455B), any acid rain compliance option for conditional approval; provided that an acid rain compliance option under Section

407 of the Act may be conditionally proposed only to the extent provided in regulations implementing Section 407 of the Act.

a. To activate a conditionally approved acid rain compliance option, the designated representative shall notify the department in writing that the conditionally approved compliance option will actually be pursued beginning January 1 of a specified year. If the conditionally approved compliance option includes a plan described in paragraph 22.131(2)“*a*,” the designated representative of each source governed by the plan shall sign and certify the notification. Such notification shall be subject to the limitations on activation under rule 567—22.132(455B) and regulations implementing Section 407 of the Act.

b. The notification under paragraph 22.131(3)“*a*” shall specify the first calendar year and the last calendar year for which the conditionally approved acid rain compliance option is to be activated. A conditionally approved compliance option shall be activated, if at all, before the date of any enforceable milestone applicable to the compliance option. The date of activation of the compliance option shall not be a defense against failure to meet the requirements applicable to that compliance option during each calendar year for which the compliance option is activated.

c. Upon submission of a notification meeting the requirements of paragraphs 22.131(3)“*a*” and “*b*,” the conditionally approved acid rain compliance option becomes binding on the owners and operators and the designated representative of any unit governed by the conditionally approved compliance option.

d. A notification meeting the requirements of paragraphs 22.131(3)“*a*” and “*b*” will revise the unit’s permit in accordance with rule 567—22.143(455B) (administrative permit amendment).

22.131(4) Termination of compliance option.

a. The designated representative for a unit may terminate an acid rain compliance option by notifying the department in writing that an approved compliance option will be terminated beginning January 1 of a specified year. Such notification shall be subject to the limitations on termination under rule 567—22.132(455B) and regulations implementing Section 407 of the Act. If the compliance option includes a plan described in paragraph 22.131(2)“*a*,” the designated representative for each source governed by the plan shall sign and certify the notification.

b. The notification under paragraph 22.131(4)“*a*” shall specify the calendar year for which the termination will take effect.

c. Upon submission of a notification meeting the requirements of paragraphs 22.131(4)“*a*” and “*b*,” the termination becomes binding on the owners and operators and the designated representative of any unit governed by the acid rain compliance option to be terminated.

d. A notification meeting the requirements of paragraphs 22.131(4)“*a*” and “*b*” will revise the unit’s permit in accordance with rule 567—22.143(455B) (administrative permit amendment).

567—22.132(455B) Repowering extensions. Rescinded IAB 4/8/98, effective 5/13/98.

567—22.133(455B) Acid rain permit contents—general.

22.133(1) Each acid rain permit (including any draft acid rain permit) will contain the following elements:

a. All elements required for a complete acid rain permit application under rule 567—22.129(455B), as approved or adjusted by the department;

b. The applicable acid rain emissions limitation for sulfur dioxide; and

c. The applicable acid rain emissions limitation for nitrogen oxides.

22.133(2) Each acid rain permit is deemed to incorporate the definitions of terms under rule 567—22.120(455B).

567—22.134(455B) Acid rain permit shield. Each affected unit operated in accordance with the acid rain permit that governs the unit and that was issued in compliance with Title IV of the Act, as provided in rules 567—22.120(455B) to 567—22.146(455B), rule 567—25.2(455B), or 40 CFR Parts 72, 73, 75,

76, 77, and 78, and the regulations implementing Section 407 of the Act, shall be deemed to be operating in compliance with the acid rain program, except as provided in paragraph 22.125(7) “f.”

567—22.135(455B) Acid rain permit issuance procedures—general. The department will issue or deny all acid rain permits in accordance with rules 567—22.100(455B) to 567—22.116(455B), including the completeness determination, draft permit, administrative record, statement of basis, public notice and comment period, public hearing, proposed permit, permit issuance, permit revision, and appeal procedures as amended by rules 567—22.135(455B) to 567—22.145(455B).

567—22.136(455B) Acid rain permit issuance procedures—completeness. The department will submit a written notice of application completeness to the administrator within ten working days following a determination by the department that the acid rain permit application is complete.

567—22.137(455B) Acid rain permit issuance procedures—statement of basis.

22.137(1) The statement of basis will briefly set forth significant factual, legal, and policy considerations on which the department relied in issuing or denying the draft acid rain permit.

22.137(2) The statement of basis will include the reasons, and supporting authority, for approval or disapproval of any compliance options requested in the permit application, including references to applicable statutory or regulatory provisions and to the administrative record.

22.137(3) The department will submit to the administrator a copy of the draft acid rain permit and the statement of basis and all other relevant portions of the Title V operating permit that may affect the draft acid rain permit.

567—22.138(455B) Issuance of acid rain permits.

22.138(1) Proposed permit. After the close of the public comment and EPA 45-day review period (pursuant to subrules 22.107(6) and 22.107(7)), the department will address any objections by the administrator, incorporate all necessary changes and issue or deny the acid rain permit.

22.138(2) The department will submit the proposed acid rain permit or denial of a proposed acid rain permit to the administrator in accordance with rules 567—22.100(455B) to 567—22.116(455B), the provisions of which shall be treated as applying to the issuance or denial of a proposed acid rain permit.

22.138(3) Following the administrator’s review of the proposed acid rain permit or denial of a proposed acid rain permit, the department, or under 40 CFR 70.8(c) as amended to July 21, 1992, the administrator, will incorporate any required changes and issue or deny the acid rain permit in accordance with rules 567—22.133(455B) and 567—22.134(455B).

22.138(4) No acid rain permit including a draft or proposed permit shall be issued unless the administrator has received a certificate of representation for the designated representative of the source in accordance with Subpart B of 40 CFR Part 72.

22.138(5) Permit issuance deadline and effective date.

a. On or before December 31, 1997, the department will issue an acid rain permit to each affected source whose designated representative submitted a timely and complete acid rain permit application by January 1, 1996, in accordance with rule 567—22.126(455B) and meets the requirements of rules 567—22.135(455B) to 567—22.139(455B) and rules 567—22.100(455B) to 567—22.116(455B).

b. Nitrogen oxides. Not later than January 1, 1999, the department will reopen the acid rain permit to add the acid rain program nitrogen oxides requirements; provided that the designated representative of the affected source submitted a timely and complete acid rain permit application for nitrogen oxides in accordance with rule 567—22.126(455B). Such reopening shall not affect the term of the acid rain portion of a Title V operating permit.

c. Each acid rain permit issued in accordance with paragraph 22.138(5) “a” shall take effect by the later of January 1, 2000, or, where the permit governs a unit under paragraph 22.122(1) “c,” the deadline for monitor certification under rule 567—25.2(455B).

d. Each acid rain permit shall have a term of five years commencing on its effective date.

e. An acid rain permit shall be binding on any new owner or operator or designated representative of any source or unit governed by the permit.

22.138(6) Each acid rain permit shall contain all applicable acid rain requirements, shall be a portion of the Title V operating permit that is complete and segregable from all other air quality requirements, and shall not incorporate information contained in any other documents, other than documents that are readily available.

22.138(7) Invalidation of the acid rain portion of a Title V operating permit shall not affect the continuing validity of the rest of the Title V operating permit, nor shall invalidation of any other portion of the Title V operating permit affect the continuing validity of the acid rain portion of the permit.

567—22.139(455B) Acid rain permit appeal procedures.

22.139(1) Appeals of the acid rain portion of a Title V operating permit issued by the department that do not challenge or involve decisions or actions of the administrator under 40 CFR Parts 72, 73, 75, 76, 77, and 78 and Sections 407 and 410 of the Act and regulations implementing Sections 407 and 410 shall be conducted according to the procedures in Iowa Code chapter 17A and 561—Chapter 7, as adopted by reference at 567—Chapter 7. Appeals of the acid rain portion of such a permit that challenge or involve such decisions or actions of the administrator shall follow the procedures under 40 CFR Part 78 and Section 307 of the Act. Such decisions or actions include, but are not limited to, allowance allocations, determinations concerning alternative monitoring systems, and determinations of whether a technology is a qualifying repowering technology.

22.139(2) No administrative appeal or judicial appeal of the acid rain portion of a Title V operating permit shall be allowed more than 30 days following respective issuance of the acid rain portion of the permit that is subject to administrative appeal or issuance of the final agency action subject to judicial appeal.

22.139(3) The administrator may intervene as a matter of right in any state administrative appeal of an acid rain permit or denial of an acid rain permit.

22.139(4) No administrative appeal concerning an acid rain requirement shall result in a stay of the following requirements:

- a.* The allowance allocations for any year during which the appeal proceeding is pending or is being conducted;
- b.* Any standard requirement under rule 567—22.125(455B);
- c.* The emissions monitoring and reporting requirements applicable to the affected units at an affected source under rule 567—25.2(455B);
- d.* Uncontested provisions of the decision on appeal; and
- e.* The terms of a certificate of representation submitted by a designated representative under Subpart B of 40 CFR Part 72.

22.139(5) The department will serve written notice on the administrator of any state administrative or judicial appeal concerning an acid rain provision of any Title V operating permit or denial of an acid rain portion of any Title V operating permit within 30 days of the filing of the appeal.

22.139(6) The department will serve written notice on the administrator of any determination or order in a state administrative or judicial proceeding that interprets, modifies, voids, or otherwise relates to any portion of an acid rain permit. Following any such determination or order, the administrator will have an opportunity to review and veto the acid rain permit or revoke the permit for cause in accordance with subrules 22.107(7) and 22.107(8).

567—22.140(455B) Permit revisions—general.

22.140(1) Rules 567—22.140(455B) to 567—22.145(455B) shall govern revisions to any acid rain permit issued by the department.

22.140(2) A permit revision may be submitted for approval at any time. No permit revision shall affect the term of the acid rain permit to be revised. No permit revision shall excuse any violation of an acid rain program requirement that occurred prior to the effective date of the revision.

22.140(3) The terms of the acid rain permit shall apply while the permit revision is pending.

22.140(4) Any determination or interpretation by the state (including the department or a state court) modifying or voiding any acid rain permit provision shall be subject to review by the administrator in accordance with 40 CFR 70.8(c) as amended to July 21, 1992, as applied to permit modifications, unless the determination or interpretation is an administrative amendment approved in accordance with rule 567—22.143(455B).

22.140(5) The standard requirements of rule 567—22.125(455B) shall not be modified or voided by a permit revision.

22.140(6) Any permit revision involving incorporation of a compliance option that was not submitted for approval and comment during the permit issuance process, or involving a change in a compliance option that was previously submitted, shall meet the requirements for applying for such compliance option under rule 567—22.132(455B) and Section 407 of the Act and regulations implementing Section 407 of the Act.

22.140(7) For permit revisions not described in rules 567—22.141(455B) and 567—22.142(455B), the department may, in its discretion, determine which of these rules is applicable.

567—22.141(455B) Permit modifications.

22.141(1) Permit modifications shall follow the permit issuance requirements of rules 567—22.135(455B) to 567—22.139(455B) and subrules 22.113(2) and 22.113(3).

22.141(2) For purposes of applying subrule 22.141(1), a permit modification shall be treated as an acid rain permit application, to the extent consistent with rules 567—22.140(455B) to 567—22.145(455B).

22.141(3) The following permit revisions are permit modifications:

- a. Relaxation of an excess emission offset requirement after approval of the offset plan by the administrator;
- b. Incorporation of a final nitrogen oxides alternative emissions limitation following a demonstration period;
- c. Determinations concerning failed repowering projects under subrule 22.132(6); and
- d. At the option of the designated representative submitting the permit revision, the permit revisions listed in subrule 22.142(2).

567—22.142(455B) Fast-track modifications.

22.142(1) Fast-track modifications shall follow the following procedures:

a. The designated representative shall serve a copy of the fast-track modification on the administrator, the department, and any person entitled to a written notice under subrules 22.107(6) and 22.107(7). Within five business days of serving such copies, the designated representative shall also give public notice by publication in a newspaper of general circulation in the area where the source is located or in a state publication designed to give general public notice.

b. The public shall have a period of 30 days, commencing on the date of publication of the notice, to comment on the fast-track modification. Comments shall be submitted in writing to the air quality bureau of the department and to the designated representative.

c. The designated representative shall submit the fast-track modification to the department on or before commencement of the public comment period.

d. Within 30 days of the close of the public comment period, the department will consider the fast-track modification and the comments received and approve, in whole or in part or with changes or conditions as appropriate, or disapprove the modification. A fast-track modification shall be effective immediately upon issuance, in accordance with subrule 22.113(2) as applied to significant modifications.

22.142(2) The following permit revisions are, at the option of the designated representative submitting the permit revision, either fast-track modifications under this rule or permit modifications under rule 567—22.141(455B):

- a. Incorporation of a compliance option that the designated representative did not submit for approval and comment during the permit issuance process;
- b. Addition of a nitrogen oxides averaging plan to a permit; and

c. Changes in a repowering plan, nitrogen oxides averaging plan, or nitrogen oxides compliance deadline extension.

567—22.143(455B) Administrative permit amendment.

22.143(1) Administrative amendments shall follow the procedures set forth at rule 567—22.111(455B). The department will submit the revised portion of the permit to the administrator within ten working days after the date of final action on the request for an administrative amendment.

22.143(2) The following permit revisions are administrative amendments:

a. Activation of a compliance option conditionally approved by the department; provided that all requirements for activation under subrule 22.131(3) and rule 567—22.132(455B) are met;

b. Changes in the designated representative or alternative designated representative; provided that a new certificate of representation is submitted to the administrator in accordance with Subpart B of 40 CFR Part 72;

c. Correction of typographical errors;

d. Changes in names, addresses, or telephone or facsimile numbers;

e. Changes in the owners or operators; provided that a new certificate of representation is submitted within 30 days to the administrator and the department in accordance with Subpart B of 40 CFR Part 72;

f. Termination of a compliance option in the permit; provided that all requirements for termination under subrule 22.131(4) shall be met and this procedure shall not be used to terminate a repowering plan after December 31, 1999;

g. Changes in the date, specified in a new unit's acid rain permit, of commencement of operation or the deadline for monitor certification; provided that they are in accordance with rule 567—22.125(455B);

h. The addition of or change in a nitrogen oxides alternative emissions limitation demonstration period; provided that the requirements of regulations implementing Section 407 of the Act are met; and

i. Incorporation of changes that the administrator has determined to be similar to those in paragraphs "a" through "h" of this subrule.

567—22.144(455B) Automatic permit amendment. The following permit revisions shall be deemed to amend automatically, and become a part of the affected unit's acid rain permit by operation of law without any further review:

22.144(1) Upon recordation by the administrator under 40 CFR Part 73, all allowance allocations to, transfers to, and deductions from an affected unit's allowance tracking system account; and

22.144(2) Incorporation of an offset plan that has been approved by the administrator under 40 CFR Part 77.

567—22.145(455B) Permit reopenings.

22.145(1) As provided in rule 567—22.114(455B), the department will reopen an acid rain permit for cause, including whenever additional requirements become applicable to any affected unit governed by the permit.

22.145(2) In reopening an acid rain permit for cause, the department will issue a draft permit changing the provisions, or adding the requirements, for which the reopening was necessary. The draft permit shall be subject to the requirements of rules 567—22.135(455B) to 567—22.139(455B).

22.145(3) Any reopening of an acid rain permit shall not affect the term of the permit.

567—22.146(455B) Compliance certification—annual report.

22.146(1) Applicability and deadline. For each calendar year in which a unit is subject to the acid rain emissions limitations, the designated representative of the source at which the unit is located shall submit to the administrator and the department, within 60 days after the end of the calendar year, an annual compliance certification report for the unit in compliance with 40 CFR 72.90.

22.146(2) The submission of complete compliance certifications in accordance with subrule 22.146(1) and rule 567—25.2(455B) shall be deemed to satisfy the requirement to submit compliance

certifications under paragraph 22.108(15) “e” with regard to the acid rain portion of the source’s Title V operating permit.

567—22.147(455B) Compliance certification—units with repowering extension plans. Rescinded IAB 4/8/98, effective 5/13/98.

567—22.148(455B) Sulfur dioxide opt-ins. The department adopts by reference the provisions of 40 CFR Part 74, Acid Rain Opt-Ins.

567—22.149 to 22.199 Reserved.

567—22.200(455B) Definitions for voluntary operating permits. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.201(455B) Eligibility for voluntary operating permits. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.202(455B) Requirement to have a Title V permit. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.203(455B) Voluntary operating permit applications. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.204(455B) Voluntary operating permit fees. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.205(455B) Voluntary operating permit processing procedures. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.206(455B) Permit content. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.207(455B) Relation to construction permits. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.208(455B) Suspension, termination, and revocation of voluntary operating permits. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.209(455B) Change of ownership for facilities with voluntary operating permits. Rescinded ARC 1913C, IAB 3/18/15, effective 4/22/15.

567—22.210 to 22.299 Reserved.

567—22.300(455B) Operating permit by rule for small sources. Except as provided in subrule 22.300(11), any source which otherwise would be required to obtain a Title V operating permit may instead register for an operation permit by rule for small sources. Sources which comply with the requirements contained in this rule will be deemed to have an operating permit by rule for small sources. Sources which comply with this rule will be considered to have federally enforceable limits so that their potential emissions are less than the major source thresholds for regulated air pollutants and hazardous air pollutants as defined in rule 567—22.100(455B).

22.300(1) Definitions for operating permit by rule for small sources. For the purposes of rule 567—22.300(455B), the definitions shall be the same as the definitions found at rule 567—22.100(455B).

22.300(2) Registration for operating permit by rule for small sources.

a. Except as provided in subrules 22.300(3) and 22.300(11), any person who owns or operates a stationary source and meets the following criteria may register for an operating permit by rule for small sources:

(1) The potential to emit air contaminants is equal to or in excess of the threshold for a major stationary source of regulated air pollutants or hazardous air pollutants, and

(2) For every 12-month rolling period, the actual emissions of the stationary source are less than or equal to the emission limitations specified in subrule 22.300(6).

b. Eligibility for an operating permit by rule for small sources does not eliminate the source's responsibility to meet any and all applicable federal requirements including, but not limited to, a maximum achievable control technology (MACT) standard.

c. Nothing in this rule shall prevent any stationary source which has had a Title V operating permit from qualifying to comply with this rule in the future in lieu of maintaining an application for a Title V operating permit or upon rescission of a Title V operating permit if the owner or operator demonstrates that the stationary source is in compliance with the emissions limitations in subrule 22.300(6).

d. The department reserves the right to require proof that the expected emissions from the stationary source, in conjunction with all other emissions, will not prevent the attainment or maintenance of the ambient air quality standards specified in 567—Chapter 28.

22.300(3) Exceptions to eligibility.

a. Any affected source subject to the provisions of Title IV of the Act or any solid waste incinerator unit required to obtain a Title V operating permit under Section 129(e) of the Act is not eligible for an operating permit by rule for small sources.

b. Sources which meet the registration criteria established in 22.300(2)“a” and meet all applicable requirements of rule 567—22.300(455B), and are subject to a standard or other requirement under 567—subrule 23.1(2) (standards of performance for new stationary sources) or Section 111 of the Act are eligible for an operating permit by rule for small sources. These sources shall be required to obtain a Title V operating permit when the exemptions specified in subrule 22.102(1) or 22.102(2) no longer apply.

c. Sources which meet the registration criteria established in 22.300(2)“a” and meet all applicable requirements of rule 567—22.300(455B), and are subject to a standard or other requirement under 567—subrule 23.1(3) (emissions standards for hazardous air pollutants), 567—subrule 23.1(4) (emissions standards for hazardous air pollutants for source categories) or Section 112 of the Act are eligible for an operating permit by rule for small sources. These sources shall be required to obtain a Title V operating permit when the exemptions specified in subrule 22.102(1) or 22.102(2) no longer apply.

22.300(4) Stationary source with de minimus emissions. Stationary sources with de minimus emissions must submit the standard registration form and must meet and fulfill all registration and reporting requirements as found in 22.300(8). Only the record-keeping and reporting provisions listed in 22.300(4)“b” shall apply to a stationary source with de minimus emissions or operations as specified in 22.300(4)“a”:

a. *De minimus emission and usage limits.* For the purpose of this rule a stationary source with de minimus emissions means:

(1) In every 12-month rolling period, the stationary source emits less than or equal to the following quantities of emissions:

1. 5 tons per year of a regulated air pollutant (excluding HAPs), and
2. 2 tons per year of a single HAP, and
3. 5 tons per year of any combination of HAPs.

(2) In every 12-month rolling period, at least 90 percent of the stationary source's emissions are associated with an operation for which the throughput is less than or equal to one of the quantities specified in paragraphs “1” to “9” below:

1. 1,400 gallons of any combination of solvent-containing materials but no more than 550 gallons of any one solvent-containing material, provided that the materials do not contain the following:

methyl chloroform (1,1,1-trichloroethane), methylene chloride (dichloromethane), tetrachloroethylene (perchloroethylene), or trichloroethylene;

2. 750 gallons of any combination of solvent-containing materials where the materials contain the following: methyl chloroform (1,1,1-trichloroethane), methylene chloride (dichloromethane), tetrachloroethylene (perchloroethylene), or trichloroethylene, but not more than 300 gallons of any one solvent-containing material;

3. 365 gallons of solvent-containing material used at a paint spray unit(s);

4. 4,400,000 gallons of gasoline dispensed from equipment with Phase I and II vapor recovery systems;

5. 470,000 gallons of gasoline dispensed from equipment without Phase I and II vapor recovery systems;

6. 1,400 gallons of gasoline combusted;

7. 16,600 gallons of diesel fuel combusted;

8. 500,000 gallons of distillate oil combusted; or

9. 71,400,000 cubic feet of natural gas combusted.

b. Record keeping for de minimis sources. Upon registration with the department the owner or operator of a stationary source eligible to register for an operating permit by rule for small sources shall comply with all applicable record-keeping requirements of this rule. The record-keeping requirements of this rule shall not replace any record-keeping requirement contained in a construction permit or in a local, state, or federal rule or regulation.

(1) De minimis sources shall always maintain an annual log of each raw material used and its amount. The annual log and all related material safety data sheets (MSDS) for all materials shall be maintained for a period of not less than the most current five years. The annual log will begin on the date the small source operating permit application is submitted, then on an annual basis, based on a calendar year.

(2) Within 30 days of a written request by the state or the U.S. EPA, the owner or operator of a stationary source not maintaining records pursuant to subrule 22.300(7) shall demonstrate that the stationary source's emissions or throughput is not in excess of the applicable quantities set forth in paragraph "a" above.

22.300(5) Provision for air pollution control equipment. The owner or operator of a stationary source may take into account the operation of air pollution control equipment on the capacity of the source to emit an air contaminant if the equipment is required by federal, state, or local air pollution control agency rules and regulations or permit terms and conditions that are federally enforceable. The owner or operator of the stationary source shall maintain and operate such air pollution control equipment in a manner consistent with good air pollution control practice for minimizing emissions.

22.300(6) Emission limitations.

a. No stationary source subject to this rule shall emit in every 12-month rolling period more than the following quantities of emissions:

(1) 50 percent of the major source thresholds for regulated air pollutants (excluding hazardous air pollutants), and

(2) 5 tons per year of a single hazardous air pollutant, and

(3) 12.5 tons per year of any combination of hazardous air pollutants.

b. The owner or operator of a stationary source subject to this rule shall obtain any necessary permits prior to commencing any physical or operational change or activity which will result in actual emissions that exceed the limits specified in paragraph "a" of this subrule.

22.300(7) Record-keeping requirements for non-de minimis sources. Upon registration with the department the owner or operator of a stationary source eligible to register for an operating permit by rule for small stationary sources shall comply with all applicable record-keeping requirements in this rule. The record-keeping requirements of this rule shall not replace any record-keeping requirement contained in any operating permit, a construction permit, or in a local, state, or federal rule or regulation.

a. A stationary source previously covered by the provisions in 22.300(4) shall comply with the applicable provisions of subrule 22.300(7) (record-keeping requirements) and subrule 22.300(8)

(reporting requirements) if the stationary source exceeds the quantities specified in paragraph 22.300(4)“a.”

b. The owner or operator of a stationary source subject to this rule shall keep and maintain records, as specified in 22.300(7)“c” below, for each permitted emission unit and each piece of emission control equipment sufficient to determine actual emissions. Such information shall be maintained on site for five years, and be made available to local, state, or U.S. EPA staff upon request.

c. Record-keeping requirements for emission units and emission control equipment. Record-keeping requirements for emission units are specified below in 22.300(7)“c”(1) through 22.300(7)“c”(4). Record-keeping requirements for emission control equipment are specified in 22.300(7)“c”(5).

(1) Coating/solvent emission unit. The owner or operator of a stationary source subject to this rule that contains a coating/solvent emission unit not permitted under 22.8(1) (permit by rule for spray booths) or uses a coating, solvent, ink or adhesive shall keep and maintain the following records:

1. A current list of all coatings, solvents, inks and adhesives in use. This list shall include: material safety data sheets (MSDS), manufacturer’s product specifications, and material VOC content reports for each solvent (including solvents used in cleanup and surface preparation), coating, ink, and adhesive used showing at least the product manufacturer, product name and code, VOC and hazardous air pollutant content;

2. A description of any equipment used during and after coating/solvent application, including type, make and model; maximum design process rate or throughput; and control device(s) type and description (if any);

3. A monthly log of the consumption of each solvent (including solvents used in cleanup and surface preparation), coating, ink, and adhesive used; and

4. All purchase orders, invoices, and other documents to support information in the monthly log.

(2) Organic liquid storage unit. The owner or operator of a stationary source subject to this rule that contains an organic liquid storage unit shall keep and maintain the following records:

1. A monthly log identifying the liquid stored and monthly throughput; and

2. Information on the tank design and specifications including control equipment.

(3) Combustion emission unit. The owner or operator of a stationary source subject to this rule that contains a combustion emission unit shall keep and maintain the following records:

1. Information on equipment type, make and model, maximum design process rate or maximum power input/output, minimum operating temperature (for thermal oxidizers) and capacity and all source test information; and

2. A monthly log of fuel type, fuel usage, fuel heating value (for nonfossil fuels; in terms of Btu/lb or Btu/gal), and percent sulfur for fuel oil and coal.

(4) General emission unit. The owner or operator of a stationary source subject to this rule that contains an emission unit not included in subparagraph (1), (2), or (3) above shall keep and maintain the following records:

1. Information on the process and equipment including the following: equipment type, description, make and model; and maximum design process rate or throughput;

2. A monthly log of operating hours and each raw material used and its amount; and

3. Purchase orders, invoices, or other documents to support information in the monthly log.

(5) Emission control equipment. The owner or operator of a stationary source subject to this rule that contains emission control equipment shall keep and maintain the following records:

1. Information on equipment type and description, make and model, and emission units served by the control equipment;

2. Information on equipment design including, where applicable: pollutant(s) controlled; control effectiveness; and maximum design or rated capacity; other design data as appropriate including any available source test information and manufacturer’s design/repair/maintenance manual; and

3. A monthly log of hours of operation including notation of any control equipment breakdowns, upsets, repairs, maintenance and any other deviations from design parameters.

22.300(8) Registration and reporting requirements.

a. Duty to apply. Any person who owns or operates a source otherwise required to obtain a Title V operating permit and which would be eligible for an operating permit by rule for small sources must either register for an operating permit by rule for small sources or apply for a Title V operating permit. Any source determined not to be eligible for an operating permit by rule for small sources, and operating without a valid Title V operating permit, shall be subject to enforcement action for operation without a Title V operating permit, except as provided for in the application shield provisions contained in rule 567—22.104(455B). For each source registering for an operating permit by rule for small sources, the owner or operator or designated representative, where applicable, shall present or mail to the Air Quality Bureau, Iowa Department of Natural Resources, 502 East 9th Street, Des Moines, Iowa 50319, one original and one copy of a timely and complete registration form in accordance with this rule.

(1) Timely registration. Each source registering for an operating permit by rule for small sources shall submit a registration form:

1. By August 1, 1996, if the source became subject to rule 567—22.101(455B) on or before August 1, 1995, unless otherwise required to obtain a Title V permit under rule 567—22.101(455B).

2. Within 12 months of becoming subject to rule 567—22.101(455B) (the requirement to obtain a Title V operating permit) for a new source or a source which would otherwise become subject to the Title V permit requirement after August 1, 1995.

(2) Complete registration form. To be deemed complete the registration form must provide all information required pursuant to 22.300(8)“*b.*”

(3) Duty to supplement or correct registration. Any registrant who fails to submit any relevant facts or who has submitted incorrect information in an operating permit by rule for small sources registration shall, upon becoming aware of such failure or incorrect submittal, promptly submit such supplementary facts or corrected information. In addition, the registrant shall provide additional information as necessary to address any requirements that become applicable to the source after the date it filed a complete registration.

(4) Certification of truth, accuracy, and completeness. Any registration form, report, or supplemental information submitted pursuant to these rules shall contain certification by a responsible official of truth, accuracy, and completeness. This certification and any other certification required under these rules shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

b. At the time of registration for an operating permit by rule for small sources each owner or operator of a stationary source shall submit to the department a standard registration form and required attachments. To register for an operating permit by rule for small sources, applicants shall complete the registration form and supply all information required by the filing instructions. The information submitted must be sufficient to evaluate the source, its registration, predicted actual emissions from the source; and to determine whether the source is subject to the exceptions listed in subrule 22.300(3). The standard registration form and attachments shall require that the following information be provided:

(1) Identifying information, including company name and address (or plant or source name if different from the company name), owner’s name and responsible official, and telephone number and names of plant site manager or contact;

(2) A description of source processes and products;

(3) The following emissions-related information shall be submitted to the department on the standard registration form:

1. The total actual emissions of each regulated air pollutant. Actual emissions shall be reported for one contiguous 12-month period within the 18 months preceding submission of the registration to the department;

2. Identification and description of each emission unit with the potential to emit a regulated air pollutant;

3. Identification and description of air pollution control equipment;

4. Limitations on source operations affecting emissions or any work practice standards, where applicable, for all regulated pollutants;

5. Fugitive emissions sources shall be included in the registration form in the same manner as stack emissions if the source is one of the source categories defined as a stationary source category in rule 567—22.100(455B).

(4) Requirements for certification. Facilities which claim to meet the requirements set forth in this rule to qualify for an operating permit by rule for small sources must submit to the department, with a complete registration form, a written statement as follows:

“I certify that all equipment at the facility with a potential to emit any regulated pollutant is included in the registration form, and submitted to the department as required in 22.300(8) “b.” I understand that the facility will be deemed to have been granted an operating permit by rule for small sources under the terms of rule 567—22.300(455B) only if all applicable requirements of rule 567—22.300(455B) are met and if the registration is not denied by the director under rule 567—22.300(11). This certification is based on information and belief formed after reasonable inquiry; the statements and information in the document are true, accurate, and complete.” The certification must be signed by one of the following individuals.

For corporations, a principal executive officer of at least the level of vice president, or a responsible official as defined at rule 567—22.100(455B).

For partnerships, a general partner.

For sole proprietorships, the proprietor.

For municipal, state, county, or other public facilities, the principal executive officer or the ranking elected official.

22.300(9) *Construction permits issued after registration for an operating permit by rule for small sources.* This rule shall not relieve any stationary source from complying with requirements pertaining to any otherwise applicable construction permit, or to replace a condition or term of any construction permit, or any provision of a construction permitting program. This does not preclude issuance of any construction permit with conditions or terms necessary to ensure compliance with this rule.

a. If the issuance of a construction permit acts to make the source no longer eligible for an operating permit by rule for small sources, the source shall, within 12 months of issuance of the construction permit, submit an application for a Title V operating permit.

b. If the issuance of a construction permit does not prevent the source from continuing to be eligible to operate under an operating permit by rule for small sources, the source shall, within 30 days of issuance of a construction permit, provide to the department the information as listed in 22.300(8) “b” for the new or modified source.

22.300(10) *Violations.*

a. Failure to comply with any of the applicable provisions of this rule shall constitute a violation of this rule.

b. A stationary source subject to this rule shall be subject to applicable federal requirements for a major source, including rules 567—22.101(455B) to 567—22.116(455B) when the conditions specified in either subparagraph (1) or (2) below, occur:

(1) Commencing on the first day following every 12-month rolling period in which the stationary source exceeds a limit specified in subrule 22.300(6), or

(2) Commencing on the first day following every 12-month rolling period in which the owner or operator cannot demonstrate that the stationary source is in compliance with the limits in subrule 22.300(6).

22.300(11) *Suspension, termination, and revocation of an operating permit by rule for small sources.*

a. Registrations may be terminated, modified, revoked, or reissued for cause. The following examples shall be considered cause for the suspension, modification, revocation, or reissuance of an operating permit by rule for small sources:

(1) The director has reasonable cause to believe that the operating permit by rule for small sources was obtained by fraud or misrepresentation.

(2) The person registering for the operating permit by rule for small sources failed to disclose a material fact required by the registration form or the rules applicable to the operating permit by rule for

small sources, of which the applicant had or should have had knowledge at the time the registration form was submitted.

(3) The terms and conditions of the operating permit by rule for small sources have been or are being violated.

(4) The owner or operator of the source has failed to pay an administrative, civil or criminal penalty for violations of the operating permit by rule for small sources.

b. If the director suspends, terminates or revokes an operating permit by rule for small sources under this rule, the notice of such action shall be served on the applicant by certified mail, return receipt requested. The notice shall include a statement detailing the grounds for the action sought, and the proceeding shall in all other respects comply with the requirements of rule 561—7.16(17A,455A).

22.300(12) *Change of ownership.* The new owner shall notify the department in writing no later than 30 days after the change of ownership of equipment covered by an operating permit by rule for small sources. The notification to the department shall be mailed to Air Quality Bureau, Iowa Department of Natural Resources, 502 East 9th Street, Des Moines, Iowa 50319, and shall include the following information:

a. The date of ownership change; and

b. The name, address and telephone number of the responsible official, the contact person and the owner of the equipment both before and after the change of ownership.

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◊ Two or more ARCs

- ¹ Effective date of 22.1(455B) [DEQ, 3.1] delayed by the Administrative Rules Review Committee 70 days from June 21, 1978. The Administrative Rules Review Committee at the August 15, 1978 meeting delayed 22.1 [DEQ, 3.1] under provisions of 67GA, SF244, §19. (See HJR 6, 1/22/79).
- ² Effective date of 22.100(455B), definition of "12-month rolling period"; 22.200(455B); 22.201(1) "a," "b,"; 22.201(2) "a"; 22.206(2) "c," delayed 70 days by the Administrative Rules Review Committee at its meeting held October 10, 1995; delay lifted by this Committee December 13, 1995, effective December 14, 1995.
- ³ Effective date of 22.300 delayed 70 days by the Administrative Rules Review Committee at its meeting held June 11, 1996; delay lifted by this Committee at its meeting held June 12, 1996, effective June 12, 1996.
- ⁴ Effective date of 22.1(2), unnumbered introductory paragraphs and paragraphs "g" and "i," delayed 70 days by the Administrative Rules Review Committee at its meeting held March 9, 2001.

CHAPTER 23
EMISSION STANDARDS FOR CONTAMINANTS

[Prior to 7/1/83, DEQ Ch 4]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—23.1(455B) Emission standards.

23.1(1) *In general.* The federal standards of performance for new stationary sources (new source performance standards) shall be applicable as specified in subrule 23.1(2). The federal standards for hazardous air pollutants (national emission standards for hazardous air pollutants) shall be applicable as specified in subrule 23.1(3). The federal standards for hazardous air pollutants for source categories (national emission standards for hazardous air pollutants for source categories) shall be applicable as specified in subrule 23.1(4). The federal emission guidelines (emission guidelines) shall be applicable as specified in subrule 23.1(5). Compliance with emission standards specified elsewhere in this chapter shall be in accordance with 567—Chapter 21.

23.1(2) *New source performance standards.* The federal standards of performance for new stationary sources, as defined in 40 Code of Federal Regulations Part 60 as amended or corrected through November 14, 2018, are adopted by reference, except § 60.530 through § 60.539b (Part 60, Subpart AAA), and shall apply to the following affected facilities. The corresponding 40 CFR Part 60 subpart designation is in parentheses. An earlier date for adoption by reference may be included with the subpart designation in parentheses. Reference test methods (Appendix A), performance specifications (Appendix B), determination of emission rate change (Appendix C), quality assurance procedures (Appendix F) and the general provisions (Subpart A) of 40 CFR Part 60 also apply to the affected facilities.

a. Fossil fuel-fired steam generators. A fossil fuel-fired steam generating unit of more than 250 million Btu heat input for which construction, reconstruction, or modification is commenced after August 17, 1971. Any facility covered under paragraph “z” is not covered under this paragraph. (Subpart D as amended through January 20, 2011)

b. Incinerators. An incinerator of more than 50 tons per day charging rate. (Subpart E)

c. Portland cement plants. Any of the following in a Portland cement plant: kiln; clinker cooler; raw mill system; finish mill system; raw mill dryer; raw material storage; clinker storage; finished product storage; conveyor transfer points; bagging and bulk loading and unloading systems. (Subpart F)

d. Nitric acid plants. A nitric acid production unit. Unless otherwise exempted, these standards apply to any nitric acid production unit that commences construction or modification after August 17, 1971, and on or before October 14, 2011. (Subpart G)

e. Sulfuric acid plants. A sulfuric acid production unit. (Subpart H)

f. Hot mix asphalt plants. Each hot mix asphalt facility that commenced construction or modification after June 11, 1973. For the purpose of this paragraph, a hot mix asphalt facility is comprised only of any combination of the following: dryers; systems for screening, handling, storing, and weighing hot aggregate; systems for loading, transferring, and storing mineral filler; systems for mixing hot mix asphalt; and the loading, transfer, and storage systems associated with emission control systems. (Subpart I)

g. Petroleum refineries. Rescinded IAB 3/18/15, effective 4/22/15.

h. Secondary lead smelters. Rescinded IAB 3/18/15, effective 4/22/15.

i. Secondary brass and bronze ingot production plants. Any of the following at a secondary brass and bronze ingot production plant; reverberatory and electric furnaces of 1000/kilograms (2205 pounds) or greater production capacity and blast (cupola) furnaces of 250 kilograms per hour (550 pounds per hour) or greater production capacity. (Subpart M)

j. Iron and steel plants. A basic oxygen process furnace. (Subpart N)

k. Sewage treatment plants. An incinerator which burns the sludge produced by municipal sewage treatment plants. (Subpart O of 40 CFR 60 and Subpart E of 40 CFR 503.)

- l. Steel plants.* Either of the following at a steel plant: electric arc furnaces and dust-handling equipment, the construction, modification, or reconstruction of which commenced after October 21, 1974, and on or before August 17, 1983. (Subpart AA)
- m. Primary copper smelters.* Rescinded IAB 3/18/15, effective 4/22/15.
- n. Primary zinc smelters.* Rescinded IAB 3/18/15, effective 4/22/15.
- o. Primary lead smelter.* Rescinded IAB 3/18/15, effective 4/22/15.
- p. Primary aluminum reduction plants.* Rescinded IAB 3/18/15, effective 4/22/15.
- q. Wet process phosphoric acid plants in the phosphate fertilizer industry.* A wet process phosphoric acid plant, which includes any combination of the following: reactors, filters, evaporators and hotwells. (Subpart T)
- r. Superphosphoric acid plants in the phosphate fertilizer industry.* A superphosphoric acid plant which includes any combination of the following: evaporators, hotwells, acid sumps, and cooling tanks. (Subpart U)
- s. Diammonium phosphate plants in the phosphate fertilizer industry.* A granular diammonium phosphate plant which includes any combination of the following: reactors, granulators, dryers, coolers, screens and mills. (Subpart V)
- t. Triple super phosphate plants in the phosphate fertilizer industry.* A triple super phosphate plant which includes any combination of the following: mixers, curing belts (dens), reactors, granulators, dryers, cookers, screens, mills and facilities which store run-of-pile triple superphosphate. (Subpart W)
- u. Granular triple superphosphate storage facilities in the phosphate fertilizer industry.* A granular triple superphosphate storage facility which includes any combination of the following: storage or curing piles, conveyors, elevators, screens and mills. (Subpart X)
- v. Coal preparation plants.* Any of the following at a coal preparation plant which processes more than 200 tons per day: thermal dryers; pneumatic coal cleaning equipment (air tables); coal processing and conveying equipment (including breakers and crushers); coal storage systems; and coal transfer and loading systems. (Subpart Y)
- w. Ferroalloy production.* Any of the following: electric submerged arc furnaces which produce silicon metal, ferrosilicon, calcium silicon, silicomanganese zirconium, ferrochrome silicon, silvery iron, high-carbon ferrochrome, charge chrome, standard ferromanganese, silicomanganese, ferromanganese silicon, or calcium carbide; and dust-handling equipment. (Subpart Z)
- x. Kraft pulp mills.* Any of the following in a kraft pulp mill: digester system; brown stock washer system; multiple effect evaporator system; black liquor oxidation system; recovery furnace; smelt dissolving tank; lime kiln; and condensate stripper system. In pulp mills where kraft pulping is combined with neutral sulfite semichemical pulping, the provisions of the standard of performance are applicable when any portion of the material charged to an affected facility is produced by the kraft pulping operation. (Subpart BB)
- y. Lime manufacturing plants.* A rotary lime kiln or a lime hydrator used in the manufacture of lime at other than a kraft pulp mill. (Subpart HH)
- z. Electric utility steam generating units.* An electric utility steam generating unit that is capable of combusting more than 250 million Btus per hour (73 megawatts) heat input of fossil fuel for which construction or modification or reconstruction is commenced after September 18, 1978, or an electric utility combined cycle gas turbine that is capable of combusting more than 250 million Btus per hour (73 megawatts) heat input. "Electric utility steam generating unit" means any steam electric generating unit that is constructed for the purpose of supplying more than one-third of its potential electric output capacity and more than 25 MW net-electrical output to any utility power distribution system for sale. Also, any steam supplied to a steam distribution system for the purpose of providing steam to a steam electric generator that would produce electrical energy for sale is considered in determining the electrical energy output capacity of the affected facility. (Subpart Da as amended through January 20, 2011)
- aa. Stationary gas turbines.* Any simple cycle gas turbine, regenerative cycle gas turbine or any gas turbine portion of a combined cycle steam/electric generating system that is not self-propelled. It may, however, be mounted on a vehicle for portability. (Subpart GG)

- bb. Petroleum storage vessels.* Unless exempted, any storage vessel for petroleum liquids for which the construction, reconstruction, or modification commenced after June 11, 1973, and prior to May 19, 1978, having a storage capacity greater than 151,412 liters (40,000 gallons). (Subpart K)
- cc. Petroleum storage vessels.* Unless exempted, any storage vessel for petroleum liquids for which the construction, reconstruction, or modification commenced after May 18, 1978, and prior to July 23, 1984, having a storage capacity greater than 151,416 liters (40,000 gallons). (Subpart Ka)
- dd. Glass manufacturing plants.* Any glass melting furnace. (Subpart CC)
- ee. Automobile and light-duty truck surface coating operations at assembly plants.* Any of the following in an automobile or light-duty truck assembly plant: prime coat operations, guide coat operations, and topcoat operations. (Subpart MM)
- ff. Ammonium sulfate manufacture.* Any of the following in the ammonium sulfate industry: ammonium sulfate dryers in the caprolactam by-product, synthetic, and coke oven by-product sectors of the industry. (Subpart PP)
- gg. Surface coating of metal furniture.* Any metal furniture surface coating operation in which organic coatings are applied. (Subpart EE)
- hh. Lead-acid battery manufacturing plants.* Any lead-acid battery manufacturing plant which uses any of the following: grid casting, paste mixing, three-process operation, lead oxide manufacturing, lead reclamation, other lead-emitting operations. (Subpart KK)
- ii. Phosphate rock plants.* Any phosphate rock plant which has a maximum plant production capacity greater than four tons per hour including the following: dryers, calciners, grinders, and ground rock handling and storage facilities, except those facilities producing or preparing phosphate rock solely for consumption in elemental phosphorus production. (Subpart NN)
- jj. Graphic arts industry.* Publication rotogravure printing. Any publication rotogravure printing press except proof presses. (Subpart QQ)
- kk. Industrial surface coating — large appliances.* Any surface coating operation in a large appliance surface coating line. (Subpart SS)
- ll. Metal coil surface coating.* Any of the following at a metal coil surface coating operation: prime coat operation, finish coat operation, and each prime and finish coat operation combined when the finish coat is applied wet-on-wet over the prime coat and both coatings are cured simultaneously. (Subpart TT)
- mm. Asphalt processing and asphalt roofing manufacturing.* Any saturator, mineral handling and storage facility at asphalt roofing plants; and any asphalt storage tank and any blowing still at asphalt processing plants, petroleum refineries, and asphalt roofing plants. (Subpart UU)
- nn. Equipment leaks of volatile organic compounds (VOC) in the synthetic organic chemicals manufacturing industry.* Standards for affected facilities in the synthetic organic chemicals manufacturing industry (SOCMI) that commenced construction, reconstruction, or modification after January 5, 1981, and on or before November 7, 2006, are set forth in Subpart VV. Standards for affected SOCMI facilities that commenced construction, reconstruction or modification after November 7, 2006, are set forth in Subpart VVa. The standards apply to pumps, compressors, pressure relief devices, sampling systems, open-ended valves or lines (OEL), valves, and flanges or other connectors which handle VOC. (Subpart VV and Subpart VVa)
- oo. Beverage can surface coating.* Any beverage can surface coating lines for two-piece steel or aluminum containers in which soft drinks or beer are sold. (Subpart WW)
- pp. Bulk gasoline terminals.* The total of all loading racks at bulk gasoline terminals which deliver liquid product into gasoline tank trucks. (Subpart XX)
- qq. Pressure sensitive tape and label surface coating operations.* Any coating line used in the tape manufacture of pressure sensitive tape and label materials. (Subpart RR)
- rr. Metallic mineral processing plants.* Any ore processing and handling equipment. (Subpart LL)
- ss. Synthetic fiber production facilities.* Any solvent-spun synthetic fiber process that produces more than 500 megagrams of fiber per year. (Subpart HHH)
- tt. Equipment leaks of VOC in petroleum refineries.* A compressor and all equipment (defined in 40 CFR, Part 60.591) within a process unit for which the construction, reconstruction, or modification commenced after January 4, 1983. (Subpart GGG)

uu. Flexible vinyl and urethane coating and printing. Each rotogravure printing line used to print or coat flexible vinyl or urethane products. (Subpart FFF)

vv. Petroleum dry cleaners. Petroleum dry-cleaning plant with a total manufacturer's rated dryer capacity equal to or greater than 38 kilograms (84 pounds): petroleum solvent dry-cleaning dryers, washers, filters, stills, and settling tanks. (Subpart JJJ)

ww. Electric arc furnaces and argon-oxygen decarburization vessels constructed after August 17, 1983. Steel plants that produce carbon, alloy, or specialty steels: electric arc furnaces, argon-oxygen decarburization vessels, and dust-handling systems. (Subpart AAa)

xx. Wool fiberglass insulation manufacturing plants. Rotary spin wool fiberglass manufacturing line. (Subpart PPP)

yy. Iron and steel plants. Secondary emissions from basic oxygen process steelmaking facilities for which construction, reconstruction, or modification commenced after January 20, 1983. (Subpart Na)

zz. Equipment leaks of VOC from on-shore natural gas processing plants. A compressor and all equipment defined in 40 CFR, Part 60.631, unless exempted, for which construction, reconstruction, or modification commenced after January 20, 1984. (Subpart KKK)

aaa. On-shore natural gas processing: SO₂ emissions. Unless exempted, each sweetening unit and each sweetening unit followed by a sulfur recovery unit for which construction, reconstruction, or modification commenced after January 20, 1984. (Subpart LLL)

bbb. Nonmetallic mineral processing plants. Unless exempted, each crusher, grinding mill, screening operation, bucket elevator, belt conveyor, bagging operation, storage bin, enclosed truck or rail car loading station in fixed or portable nonmetallic mineral processing plants for which construction, reconstruction, or modification commenced after August 31, 1983. (Subpart OOO)

ccc. Industrial-commercial-institutional steam generating units. Unless exempted, each steam generating unit for which construction, reconstruction, or modification commenced after June 19, 1984, and which has a heat input capacity of more than 100 million Btu/hour. (Subpart Db as amended through January 20, 2011)

ddd. Volatile organic liquid storage vessels. Unless exempted, volatile organic liquid storage vessels for which construction, reconstruction, or modification commenced after July 23, 1984. (Subpart Kb)

eee. Rubber tire manufacturing plants. Unless exempted, each undertread cementing operation, each sidewall cementing operation, each tread end cementing operation, each bead cementing operation, each green tire spraying operation, each Michelin-A operation, each Michelin-B operation, and each Michelin-C automatic operation that commences construction or modification after January 20, 1983. (Subpart BBB)

fff. Industrial surface coating: surface coating of plastic parts for business machines. Each spray booth in which plastic parts for use in the manufacture of business machines receive prime coats, color coats, texture coats, or touch-up coats for which construction, modification, or reconstruction begins after January 8, 1986. (Subpart TTT)

ggg. VOC emissions from petroleum refinery wastewater systems. Each individual drain system, each oil-water separator, and each aggregate facility for which construction, modification or reconstruction is commenced after May 4, 1987. (Subpart QQQ)

hhh. Magnetic tape coating facilities. Unless exempted, each coating operation and each piece of coating mix preparation equipment for which construction, modification, or reconstruction is commenced after January 22, 1986. (Subpart SSS)

iii. Polymeric coating of supporting substrates. Unless exempted, each coating operation and any on-site coating mix preparation equipment used to prepare coatings for the polymeric coating of supporting substrates for which construction, modification, or reconstruction begins after April 30, 1987. (Subpart VVV)

jjj. VOC emissions from synthetic organic chemical manufacturing industry air oxidation unit processes. Unless exempted, any air oxidation reactor, air oxidation reactor and recovery system or combination of two or more reactors and the common recovery system used in the production of any

of the chemicals listed in 40 CFR §60.617 for which construction, modification or reconstruction commenced after October 21, 1983. (Subpart III)

kkk. VOC emissions from synthetic organic chemical manufacturing industry distillation operations. Unless exempted, any distillation unit, distillation unit and recovery system or combination of two or more distillation units and the common recovery system used in the production of any of the chemicals listed in 40 CFR §60.667 for which construction, modification or reconstruction commenced after December 30, 1983. (Subpart NNN)

lll. Small industrial-commercial-institutional steam generating units. Each steam generating unit for which construction, modification, or reconstruction is commenced after June 9, 1989, and that has a maximum design heat input capacity of 100 million Btu per hour or less, but greater than or equal to 10 million Btu per hour. (Subpart Dc as amended through January 20, 2011)

mmm. VOC emissions from the polymer manufacturing industry. Each of the following process sections in the manufacture of polypropylene and polyethylene—raw materials preparation, polymerization reaction, material recovery, product finishing, and product storage; each material recovery section of polystyrene manufacturing using a continuous process; each polymerization reaction section of poly(ethylene terephthalate) manufacturing using a continuous process; each material recovery section of poly(ethylene terephthalate) manufacturing using a continuous process that uses dimethyl terephthalate; each raw material section of poly(ethylene terephthalate) manufacturing using a continuous process that uses terephthalic acid; and each group of fugitive emissions equipment within any process unit in the manufacturing of polypropylene, polyethylene, or polystyrene (including expandable polystyrene). The applicability date for construction, modification or reconstruction for polystyrene and poly(ethylene terephthalate) affected facilities and some polypropylene and polyethylene affected facilities is September 30, 1987. For the other polypropylene and polyethylene affected facilities the applicability date for these regulations is January 10, 1989. (Subpart DDD)

nnn. Municipal waste combustors. Unless exempted, a municipal waste combustor with a capacity greater than 225 megagrams per day of municipal solid waste for which construction is commenced after December 20, 1989, and on or before September 20, 1994, and modification or reconstruction is commenced after December 20, 1989, and on or before June 19, 1996. (Subpart Ea)

ooo. Grain elevators. A grain terminal elevator or any grain storage elevator except as provided under 40 CFR 60.304(b), August 31, 1993. A grain terminal elevator means any grain elevator which has a permanent storage capacity of more than 2.5 million U.S. bushels except those located at animal food manufacturers, pet food manufacturers, cereal manufacturers, breweries, and livestock feedlots. A grain storage elevator means any grain elevator located at any wheat flour mill, wet corn mill, dry corn mill (human consumption), rice mill, or soybean oil extraction plant which has a permanent grain storage capacity of 1 million bushels. Any construction, modification, or reconstruction after August 3, 1978, is subject to this paragraph. (Subpart DD)

ppp. Mineral processing plants. Each calciner and dryer at a mineral processing plant unless excluded for which construction, modification, or reconstruction is commenced after April 23, 1986. (Subpart UUU)

qqq. VOC emissions from synthetic organic chemical manufacturing industry reactor processes. Unless exempted, each affected facility that is part of a process unit that produces any of the chemicals listed in 40 CFR §60.707 as a product, coproduct, by-product, or intermediate for which construction, modification, or reconstruction commenced after June 29, 1990. Affected facility is each reactor process not discharging its vent stream into a recovery system, each combination of a reactor process and the recovery system into which its vent stream is discharged, or each combination of two or more reactor processes and the common recovery system into which their vent streams are discharged. (Subpart RRR)

rrr. Municipal solid waste landfills, as defined by 40 CFR 60.751. Each municipal solid waste landfill that commenced construction, reconstruction or modification or began accepting waste on or after May 30, 1991, must comply. (Subpart WWW as amended through April 10, 2000)

sss. Municipal waste combustors. Unless exempted, a municipal waste combustor with a combustion capacity greater than 250 tons per day of municipal solid waste for which construction,

modification or reconstruction is commenced after September 20, 1994, or for which modification or reconstruction is commenced after June 19, 1996. (Subpart Eb)

ttt. Hospital/medical/infectious waste incinerators. Unless exempted, a hospital/medical/infectious waste incinerator for which construction is commenced after June 20, 1996, or for which modification is commenced after March 16, 1998. (Subpart Ec)*

*As of November 24, 2010, the adoption by reference of Part 60 Subpart Ec is rescinded.

uuu. New small municipal waste combustion units. Unless exempted, this standard applies to a small municipal waste combustion unit that commenced construction after August 30, 1999, or small municipal waste combustion units that commenced reconstruction or modification after June 6, 2001. (Part 60, Subpart AAAA)

vvv. Commercial and industrial solid waste incineration. Unless exempted, this standard applies to units for which construction is commenced after November 30, 1999, or for which modification or reconstruction is commenced on or after June 1, 2001. (Part 60, Subpart CCCC, as amended through December 1, 2000)

www. Other solid waste incineration (OSWI) units. Unless exempted, this standard applies to other solid waste incineration (OSWI) units for which construction is commenced after December 9, 2004, or for which modification or reconstruction is commenced on or after June 16, 2006. (Part 60, Subpart EEEE)

xxx. Reserved.

yyy. Stationary compression ignition internal combustion engines. Unless otherwise exempted, these standards apply to each stationary compression ignition internal combustion engine whose construction, modification or reconstruction commenced after July 11, 2005. (Part 60, Subpart IIII)

zzz. Stationary spark ignition internal combustion engines. These standards apply to each stationary spark ignition internal combustion engine whose construction, modification or reconstruction commenced after June 12, 2006. (Part 60, Subpart JJJJ)

aaaa. Stationary combustion turbines. Unless otherwise exempted, these standards apply to stationary combustion turbines with a heat input at peak load equal to or greater than 10 MMBtu per hour, based on the higher heating value of the fuel, that commence construction, modification, or reconstruction after February 18, 2005. (Part 60, Subpart KKKK)

bbbb. Nitric acid plants. Unless otherwise exempted, these standards apply to any nitric acid production unit that commenced construction, reconstruction or modification after October 14, 2011. (Subpart Ga)

cccc. Sewage sludge incineration units. Each sewage sludge incineration (SSI) unit for which construction or reconstruction commenced after October 14, 2010, or for which modification commenced after September 21, 2011, must comply. (Subpart LLLL)

23.1(3) Emission standards for hazardous air pollutants. The federal standards for emissions of hazardous air pollutants, 40 Code of Federal Regulations Part 61 as amended or corrected through August 30, 2016, and 40 CFR Part 503 as adopted on August 4, 1999, are adopted by reference, except 40 CFR §61.20 to §61.26, §61.90 to §61.97, §61.100 to §61.108, §61.120 to §61.127, §61.190 to §61.193, §61.200 to §61.205, §61.220 to §61.225, and §61.250 to §61.256, and shall apply to the following affected pollutants and facilities and activities listed below. The corresponding 40 CFR Part 61 subpart designation is in parentheses. Reference test methods (Appendix B), compliance status information requirements (Appendix A), quality assurance procedures (Appendix C) and the general provisions (Subpart A) of Part 61 also apply to the affected activities or facilities.

a. Asbestos. Any of the following involves asbestos emissions: asbestos mills, surfacing of roadways, manufacturing operations, fabricating, insulating, waste disposal, spraying applications and demolition and renovation operations. (Subpart M). Any person subject to notification requirements under this rule shall submit fees as required in 567—Chapter 30.

b. Beryllium. Rescinded IAB 3/18/15, effective 4/22/15.

c. Beryllium rocket motor firing. Rescinded IAB 3/18/15, effective 4/22/15.

d. Mercury. Any of the following involving mercury emissions: mercury ore processing facilities, mercury cell chlor-alkali plants, sludge incineration plants, sludge drying plants, and a combination of sludge incineration plants and sludge drying plants. (Subpart E)

e. Vinyl chloride. Ethylene dichloride purification and the oxychlorination reactor in ethylene dichloride plants. Vinyl chloride formation and purification in vinyl chloride plants. Any of the following involving polyvinyl chloride plants: reactor; stripper; mixing, weighing, and holding containers; monomer recovery system; sources following the stripper(s). Any of the following involving ethylene dichloride, vinyl chloride, and polyvinyl chloride plants: relief valve discharge; fugitive emission sources. (Subpart F)

f. Equipment leaks of benzene (fugitive emission sources). Any pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, flanges and other connectors, product accumulator vessels, and control devices or systems which handle benzene. (Subpart J)

g. Equipment leaks of volatile hazardous air pollutants (fugitive emission sources). Any pumps, compressors, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, flanges and other connectors, product accumulator vessels, and control devices or systems which handle volatile hazardous air pollutants. (Subpart V)

h. Inorganic arsenic emissions from arsenic trioxide and metallic arsenic production facilities. Rescinded IAB 3/18/15, effective 4/22/15.

i. Inorganic arsenic emissions from glass manufacturing plants. Each glass melting furnace (except pot furnaces) that uses commercial arsenic as a raw material. (Subpart N)

j. Inorganic arsenic emissions from primary copper smelters. Rescinded IAB 3/18/15, effective 4/22/15.

k. Benzene emissions from coke by-product recovery plants. Each of the following sources at furnace and foundry coke by-product recovery plants: tar decanters, tar storage tanks, tar-intercepting sumps, flushing-liquor circulation tanks, light-oil sumps, light-oil condensers, light-oil decanters, wash-oil decanters, wash-oil circulation tanks, naphthalene processing, final coolers, final-cooler cooling towers, and the following equipment that is intended to operate in benzene service: pumps, valves, exhausters, pressure relief devices, sampling connection systems, open-ended valves or lines, flanges or other connectors, and control devices or systems required by 40 CFR §61.135.

The provisions of this subpart also apply to benzene storage tanks, BTX storage tanks, light-oil storage tanks, and excess ammonia-liquor storage tanks at furnace coke by-product recovery plants. (Subpart L)

l. Benzene emissions from benzene storage vessels. Unless exempted, each storage vessel that is storing benzene having a specific gravity within the range of specific gravities specified in ASTM D 836-84 for Industrial Grade Benzene, ASTM D 835-85 for Refined Benzene-485, ASTM D 2359-85a for Refined Benzene-535, and ASTM D 4734-87 for Refined Benzene-545. These specifications are incorporated by reference as specified in 40 CFR §61.18. (Subpart Y)

m. Benzene emissions from benzene transfer operations. Unless exempted, the total of all loading racks at which benzene is loaded into tank trucks, rail cars, or marine vessels at each benzene production facility and each bulk terminal. (Subpart BB)

n. Benzene waste operations. Unless exempted, the provisions of this subrule apply to owners and operators of chemical manufacturing plants, coke by-product recovery plants, petroleum refineries, and facilities at which waste management units are used to treat, store, or dispose of waste generated by any of these listed facilities. (Subpart FF)

23.1(4) Emission standards for hazardous air pollutants for source categories. The federal standards for emissions of hazardous air pollutants for source categories, 40 Code of Federal Regulations Part 63 as amended or corrected through March 15, 2019, are adopted by reference, except those provisions which cannot be delegated to the states. The corresponding 40 CFR Part 63 subpart designation is in parentheses. An earlier date for adoption by reference may be included with the subpart designation in parentheses. 40 CFR Part 63, Subpart B, incorporates the requirements of Clean Air Act Sections 112(g) and 112(j) and does not adopt standards for a specific affected facility. Test

methods (Appendix A), sources defined for early reduction provisions (Appendix B), and determination of the fraction biodegraded (F_{bio}) in the biological treatment unit (Appendix C) of Part 63 also apply to the affected activities or facilities. For the purposes of this subrule, “hazardous air pollutant” has the same meaning found in rule 567—22.100(455B). For the purposes of this subrule, a “major source” means any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit, considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants, unless a lesser quantity is established, or in the case of radionuclides, where different criteria are employed. For the purposes of this subrule, an “area source” means any stationary source of hazardous air pollutants that is not a “major source” as defined in this subrule. Paragraph 23.1(4) “a,” general provisions (Subpart A) of Part 63, shall apply to owners or operators who are subject to subsequent subparts of 40 CFR Part 63 (except when otherwise specified in a particular subpart or in a relevant standard) as adopted by reference below.

a. General provisions. General provisions apply to owners or operators of affected activities or facilities except when otherwise specified in a particular subpart or in a relevant standard. (Subpart A)

b. Requirements for control technology determinations for major sources in accordance with Clean Air Act Sections 112(g) and 112(j). (40 CFR Part 63, Subpart B)

(1) Section 112(g) requirements. For the purposes of this subparagraph, the definitions shall be the same as the definitions found in 40 CFR 63.2 and 40 CFR 63.41 as amended through December 27, 1996. The owner or operator of a new or reconstructed major source of hazardous air pollutants must apply maximum achievable control technology (MACT) for new sources to the new or reconstructed major source. If the major source in question has been specifically regulated or exempted from regulation under a standard issued pursuant to Section 112(d), Section 112(h), or Section 112(j) of the Clean Air Act and incorporated in another subpart of 40 CFR Part 63, excluded in 40 CFR 63.40(e) and (f), or the owner or operator of such major source has received all necessary air quality permits for such construction or reconstruction project before June 29, 1998, then the major source in question is not subject to the requirements of this subparagraph. The owner or operator of an affected source shall apply for a construction permit as required in 567—paragraph 22.1(1) “b.” The construction permit application shall contain an application for a case-by-case MACT determination for the major source.

(2) Section 112(j) requirements. The owner or operator of a new or existing major source of hazardous air pollutants which includes one or more stationary sources included in a source category or subcategory for which the U.S. Environmental Protection Agency has failed to promulgate an emission standard within 18 months of the deadline established under CAA 112(d) must submit a MACT application (Parts 1 and 2) in accordance with the provisions of 40 CFR 63.52, as amended through April 5, 2002, by the CAA Section 112(j) deadline. In addition, the owner or operator of a new emission unit may submit an application for a Notice of MACT Approval before construction, as defined in 40 CFR 63.41, in accordance with the provisions of 567—paragraph 22.1(3) “a.”

c. Reserved.

d. Compliance extensions for early reductions of hazardous air pollutants. Compliance extensions for early reductions of hazardous air pollutants are available to certain owners or operators of an existing source who wish to obtain a compliance extension from a standard issued under Section 112(d) of the Act. (Subpart D)

e. Reserved.

f. Emission standards for organic hazardous air pollutants from the synthetic chemical manufacturing industry. These standards apply to chemical manufacturing process units that are part of a major source. These standards include applicability provisions, definitions and other general provisions that are applicable to Subparts F, G, and H of 40 CFR 63. (Subpart F)

g. Emission standards for organic hazardous air pollutants from the synthetic organic chemical manufacturing industry for process vents, storage vessels, transfer operations, and wastewater. These standards apply to all process vents, storage vessels, transfer racks, and wastewater streams within a source subject to Subpart F of 40 CFR 63. (Subpart G)

h. Emission standards for organic hazardous air pollutants for equipment leaks. These standards apply to emissions of designated organic hazardous air pollutants from specified processes that are located at a plant site that is a major source. Affected equipment includes: pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems and control devices or systems required by this subpart that are intended to operate in organic hazardous air pollutant service 300 hours or more during the calendar year within a source subject to the provisions of a specific subpart in 40 CFR Part 63. In organic hazardous air pollutant or in organic HAP service means that a piece of equipment either contains or contacts a fluid (liquid or gas) that is at least 5 percent by weight of total organic HAPs as determined according to the provisions of 40 CFR Part 63.161. The provisions of 40 CFR Part 63.161 also specify how to determine that a piece of equipment is not in organic HAP service. (Subpart H)

i. Emission standards for organic hazardous air pollutants for certain processes subject to negotiated regulation for equipment leaks. These standards apply to emissions of designated organic hazardous air pollutants from specified processes (defined in 40 CFR 63.190) that are located at a plant site that is a major source. Subject equipment includes pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems at certain source categories. These standards establish the applicability of Subpart H for sources that are not classified as synthetic organic chemical manufacturing industries. (Subpart I)

j. Emission standards for hazardous air pollutants for polyvinyl chloride and copolymers production. Rescinded IAB 3/18/15, effective 4/22/15.

k. Reserved.

l. Emission standards for coke oven batteries. These standards apply to existing coke oven batteries, including by-product and nonrecovery coke oven batteries and to new coke oven batteries, or as defined in the subpart. (Subpart L)

m. Perchloroethylene air emission standards for dry cleaning facilities (40 CFR Part 63, Subpart M). These standards apply to the owner or operator of each dry cleaning facility that uses perchloroethylene (also known as perc). The specific standards applicable to dry cleaning facilities, including the compliance deadlines, are set out in the federal regulations contained in Subpart M. In general, dry cleaning facilities must meet the following requirements, which are set out in greater detail in Subpart M:

(1) New and existing major source dry cleaning facilities are required to control emissions to the level of the maximum achievable control technology (MACT).

(2) New and existing area source dry cleaning facilities are required to control emissions to the level achieved by generally available control technologies (GACT) or management practices.

(3) New area sources that are located in residential buildings and that commence operation after July 13, 2006, are prohibited from using perc.

(4) New area sources located in residential buildings that commenced operation between December 21, 2005, and July 13, 2006, must eliminate all use of perc by July 27, 2009.

(5) Existing area sources located in residential buildings must eliminate all use of perc by December 21, 2020.

(6) New area sources that are not located in residential buildings are prohibited from operating transfer machines.

(7) Existing area sources that are not located in residential buildings are prohibited from operating transfer machines after July 27, 2008.

(8) All sources must comply with the requirements in Subpart M for emissions control, equipment specifications, leak detection and repair, work practice standards, record keeping and reporting.

n. Emission standards for chromium emissions from hard and decorative chromium electroplating and chromium anodizing tanks. These standards limit the discharge of chromium compound air emissions from existing and new hard chromium electroplating, decorative chromium electroplating, and chromium anodizing tanks at major and area sources. (Subpart N)

o. Emission standards for hazardous air pollutants for ethylene oxide commercial sterilization and fumigation operations. New and existing major source ethylene oxide commercial sterilization and fumigation operations are required to control emissions to the level of the maximum achievable control technology (MACT). New and existing area source ethylene oxide commercial sterilization and fumigation operations are required to control emissions to the level achieved by generally available control technologies (GACT). Certain sources are exempt as described in 40 CFR 63.360. (Subpart O)

p. Emission standards for primary aluminum reduction plants. Rescinded IAB 3/18/15, effective 4/22/15.

q. Emission standards for hazardous air pollutants for industrial process cooling towers. These standards apply to all new and existing industrial process cooling towers that are operated with chromium-based water treatment chemicals on or after September 8, 1994, and are either major sources or are integral parts of facilities that are major sources. (Subpart Q)

r. Emission standards for hazardous air pollutants for sources categories: gasoline distribution: (Stage 1). These standards apply to all existing and new bulk gasoline terminals and pipeline breakout stations that are major sources of hazardous air pollutants or are located at plant sites that are major sources. Bulk gasoline terminals and pipeline breakout stations located within a contiguous area or under common control with a refinery complying with 40 CFR Subpart CC are not subject to 40 CFR Subpart R standards. (Subpart R)

s. Emission standards for hazardous air pollutants for pulp and paper (noncombustion). These standards apply to pulping and bleaching process sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills. Affected sources include pulp mills and integrated mills (mills that manufacture pulp and paper/paperboard) that chemically pulp wood fiber (using kraft, sulfite, soda, or semichemical methods); pulp secondary fiber; pulp nonwood fiber; and mechanically pulp wood fiber. (Subpart S)

t. Emission standards for hazardous air pollutants: halogenated solvent cleaning. These standards require batch vapor solvent cleaning machines and in-line solvent cleaning machines to meet emission standards reflecting the application of maximum achievable control technology (MACT) for major and area sources; area source batch cold cleaning machines are required to achieve generally available control technology (GACT). The subpart regulates the emissions of the following halogenated hazardous air pollutant solvents: methylene chloride, perchloroethylene, trichloroethylene, 1,1,1-trichloroethane, carbon tetrachloride, and chloroform. (Subpart T)

u. Emission standards for hazardous air pollutants: Group I polymers and resins. Applicable to existing and new major sources that emit organic HAP during the manufacture of one or more elastomers including but not limited to producers of butyl rubber, halobutyl rubber, epichlorohydrin elastomers, ethylene propylene rubber, Hypalon™, neoprene, nitrile butadiene rubber, nitrile butadiene latex, polybutadiene rubber/styrene butadiene rubber by solution, polysulfide rubber, styrene butadiene rubber by emulsion, and styrene butadiene latex. MACT is required for major sources. (Subpart U)

v. Reserved.

w. Emission standards for hazardous air pollutants for epoxy resins production and nonnylon polyamides production. These standards apply to all existing, new and reconstructed manufacturers of basic liquid epoxy resins and manufacturers of wet strength resins that are located at a plant site that is a major source. (Subpart W)

x. National emission standards for hazardous air pollutants from secondary lead smelting. Rescinded IAB 3/18/15, effective 4/22/15.

y. Emission standards for marine tank vessel loading operations. This standard requires existing and new major sources to control emissions using maximum achievable control technology (MACT) to control hazardous air pollutants (HAP). (Subpart Y)

z. Reserved.

aa. Emission standards for hazardous air pollutants for phosphoric acid manufacturing. These standards apply to all new and existing major sources of phosphoric acid manufacturing. Affected processes include, but are not limited to, wet process phosphoric acid process lines, superphosphoric

acid process lines, phosphate rock dryers, phosphate rock calciners, and purified phosphoric acid process lines. (Subpart AA)

ab. Emission standards for hazardous air pollutants for phosphate fertilizers production. These standards apply to all new and existing major sources of phosphate fertilizer production plants. Affected processes include, but are not limited to, diammonium and monoammonium phosphate process lines, granular triple superphosphate process lines, and granular triple superphosphate storage buildings. (Subpart BB)

ac. National emission standards for hazardous air pollutants: petroleum refineries. Rescinded IAB 3/18/15, effective 4/22/15.

ad. Emission standards for hazardous air pollutants for off-site waste and recovery operations. This rule applies to major sources of HAP emissions which receive certain wastes, used oil, and used solvents from off-site locations for storage, treatment, recovery, or disposal at the facility. Maximum achievable control technology (MACT) is required to reduce HAP emissions from tanks, surface impoundments, containers, oil-water separators, individual drain systems and other material conveyance systems, process vents, and equipment leaks. Regulated entities include but are not limited to businesses that operate any of the following: hazardous waste treatment, storage, and disposal facilities; Resource Conservation and Recovery Act (RCRA) exempt hazardous wastewater treatment facilities other than publicly owned treatment works; used solvent recovery plants; RCRA exempt hazardous waste recycling operations; used oil re-refineries. The regulations also apply to federal agency facilities that operate any of the waste management or recovery operations. (Subpart DD)

ae. Emission standards for magnetic tape manufacturing operations. These standards apply to major sources performing magnetic tape manufacturing operations. (Subpart EE)

af. Reserved.

ag. National emission standards for hazardous air pollutants for source categories: aerospace manufacturing and rework facilities. These standards apply to major sources involved in the manufacture, repair, or rework of aerospace components and assemblies, including but not limited to airplanes, helicopters, missiles, and rockets for civil, commercial, or military purposes. Hazardous air pollutants regulated under this standard include chromium, cadmium, methylene chloride, toluene, xylene, methyl ethyl ketone, ethylene glycol, and glycol ethers. (Subpart GG)

ah. Emission standards for hazardous air pollutants for oil and natural gas production. These standards apply to all new and existing major sources of oil and natural gas production. Affected sources include, but are not limited to, processing of liquid or gaseous hydrocarbons, such as ethane, propane, butane, pentane, natural gas, and condensate extracted from field natural gas. (Subpart HH)

ai. Emission standards for hazardous air pollutants for shipbuilding and ship repair (surface coating) operations. Rescinded IAB 3/18/15, effective 4/22/15.

aj. Emission standards for hazardous air pollutants for hazardous air pollutant (HAP) emissions from wood furniture manufacturing operations. These standards apply to each facility that is engaged, either in part or in whole, in the manufacture of wood furniture or wood furniture components and that is located at a plant site that is a major source. (Subpart JJ)

ak. Emission standards for hazardous air pollutants for the printing and publishing industry. Existing and new major sources are required to control hazardous air pollutants (HAP) using the maximum achievable control technology (MACT). Affected units are publication rotogravure, product and packaging rotogravure, and wide-web flexographic printing. (Subpart KK)

al. Emission standards for hazardous air pollutants for primary aluminum reduction plants. Rescinded IAB 3/18/15, effective 4/22/15.

am. Emission standards for hazardous air pollutants for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills. (Part 63, Subpart MM)

an. Reserved.

ao. Emission standards for tanks – level 1. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general

provisions (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Part 63, Subpart OO)

ap. Emission standards for containers. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Part 63, Subpart PP)

aq. Emission standards for surface impoundments. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Part 63, Subpart QQ)

ar. Emission standards for individual drain systems. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Part 63, Subpart RR)

as. Emission standards for closed vent systems, control devices, recovery devices and routing to a fuel gas system or a process. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions, (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Subpart SS)

at. Emission standards for equipment leaks—control level 1. These provisions apply to the control of air emissions from equipment leaks for which another paragraph under this rule references the use of this paragraph for such emission control. These air emission standards for equipment leaks are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions, (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Subpart TT)

au. Emission standards for equipment leaks—control level 2 standards. These provisions apply to the control of air emissions from equipment leaks for which another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards for equipment leaks are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions, (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Subpart UU)

av. Emission standards for oil-water separators and organic-water separators. These provisions apply when another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Part 63, Subpart VV)

aw. Emission standards for storage vessels (tanks)—control level 2. These provisions apply to the control of air emissions from storage vessels for which another paragraph under this rule references the use of this paragraph for such air emission control. These air emission standards for storage vessels are placed here for administrative convenience and only apply to those owners and operators of facilities subject to the referencing paragraph. The provisions of paragraph 23.1(4)“a,” general provisions, (Subpart A), do not apply to this paragraph except as specified in a referencing paragraph. (Subpart WW)

ax. Emission standards for ethylene manufacturing process units: heat exchange systems and waste operations. This standard applies to hazardous air pollutants (HAPs) from heat exchange systems and waste streams at new and existing ethylene production units. (Part 63, Subpart XX)

ay. Emission standards for hazardous air pollutants: generic maximum achievable control technology (Generic MACT). These standards apply to new and existing major sources of acetal resins (AR) production, acrylic and modacrylic fiber (AMF) production, hydrogen fluoride (HF) production, polycarbonate (PC) production, carbon black production, cyanide chemicals manufacturing, ethylene production, and Spandex production. Affected processes include, but are not limited to, producers of homopolymers and copolymers of alternating oxymethylene units, acrylic fiber, modacrylic fiber synthetics composed of acrylonitrile (AN) units, hydrogen fluoride and polycarbonate. (Subpart YY)

az. to bb. Reserved.

bc. Emission standards for hazardous air pollutants for steel pickling—HCL process facilities and hydrochloric acid regeneration plants. Rescinded IAB 3/18/15, effective 4/22/15.

bd. Emission standards for hazardous air pollutants for mineral wool production. These standards apply to all new and existing major sources of mineral wool production. Affected processes include, but are not limited to, cupolas and curing ovens. (Subpart DDD)

be. Emission standards for hazardous air pollutants from hazardous waste combustors. These standards apply to all hazardous waste combustors: hazardous waste incinerators, hazardous waste burning cement kilns, hazardous waste burning lightweight aggregate kilns, hazardous waste solid fuel boilers, hazardous waste liquid fuel boilers, and hazardous waste hydrochloric acid production furnaces, except as specified in Subpart EEE. Both area sources and major sources are subject to this subpart as of April 19, 1996, and are subject to the requirement to apply for and obtain a Title V permit. (Part 63, Subpart EEE)

bf. Reserved.

bg. Emission standards for hazardous air pollutants for pharmaceutical manufacturing. These standards apply to producers of finished dosage forms of drugs, for example, tablets, capsules, and solutions, that contain an active ingredient generally, but not necessarily, in association with inactive ingredients. Pharmaceuticals include components whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The regulations do not apply to research and development facilities. (Subpart GGG)

bh. Emission standards for hazardous air pollutants for natural gas transmission and storage. These standards apply to all new and existing major sources of natural gas transmission and storage. Natural gas transmission and storage facilities are those that transport or store natural gas prior to its entering the pipeline to a local distribution company. Affected sources include, but are not limited to, mains, valves, meters, boosters, regulators, storage vessels, dehydrators, compressors and delivery systems. (Subpart HHH)

bi. Emission standards for hazardous air pollutants for flexible polyurethane foam production. These standards apply to producers of slabstock, molded, and rebond flexible polyurethane foam. The regulations do not apply to processes dedicated exclusively to the fabrication (i.e., gluing or otherwise bonding foam pieces together) of flexible polyurethane foam or to research and development. (Subpart III)

bj. Emission standards for hazardous air pollutants: Group IV polymers and resins. Applicable to existing and new major sources that emit organic HAP during the manufacture of the following polymers and resins: acrylonitrile butadiene styrene resin (ABS), styrene acrylonitrile resin (SAN), methyl methacrylate acrylonitrile butadiene styrene resin (MABS), methyl methacrylate butadiene styrene resin (MBS), polystyrene resin, poly (ethylene terephthalate) resin (PET), and nitrile resin. MACT is required for major sources. (Subpart JJJ)

bk. Reserved.

bl. Emission standards for hazardous air pollutants for Portland cement manufacturing operations. These standards apply to all new and existing major and area sources of Portland cement manufacturing unless exempted. Cement kiln dust (CKD) storage facilities, including CKD piles and

landfills, are excluded from this standard. Affected processes include, but are not limited to, all cement kilns and in-line kiln/raw mills, unless they burn hazardous waste. (Subpart LLL)

bm. Emission standards for hazardous air pollutants for pesticide active ingredient production. These standards apply to all new and existing major sources of pesticide active ingredient production that manufacture organic pesticide active ingredients (PAI), including herbicides, insecticides and fungicides. Affected processes include, but are not limited to, processing equipment, connected piping and ducts, associated storage vessels, pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves and connectors. Exempted sources include research and development facilities, storage vessels already subject to another 40 CFR Part 63 NESHAP, production of ethylene, storm water from segregated sewers, water from fire-fighting and deluge systems (including testing of such systems) and various spills. (Subpart MMM)

bn. Emission standards for hazardous air pollutants for wool fiberglass manufacturing. These standards apply to all new and existing major sources of wool fiberglass manufacturing. Affected processes include, but are not limited to, all glass-melting furnaces, rotary spin (RS) manufacturing lines that produce bonded building insulation, flame attenuation (FA) manufacturing lines producing bonded pipe insulation and new FA manufacturing lines producing bonded heavy-density products. (Subpart NNN)

bo. Emission standards for hazardous air pollutants for amino/phenolic resins production. These standards apply to new or existing facilities that own or operate an amino or phenolic resins production unit. (Part 63, Subpart OOO)

bp. Emission standards for hazardous air pollutants for polyether polyols production. These standards apply to all new and existing major sources of polyether polyols. Polyether polyols are compounds formed through polymerization of ethylene oxide, propylene oxide or other cyclic ethers with compounds having one or more reactive hydrogens to form polyethers. Affected processes include, but are not limited to, storage vessels, process vents, heat exchange systems, equipment leaks and wastewater operations. (Subpart PPP)

bq. Emission standards for hazardous air pollutants for primary copper smelting. Rescinded IAB 3/18/15, effective 4/22/15.

br. Emission standards for hazardous air pollutants for secondary aluminum production. (Part 63, Subpart RRR)

bs. Reserved.

bt. Emission standards for hazardous air pollutants for primary lead smelting. Rescinded IAB 3/18/15, effective 4/22/15.

bu. Emission standards for hazardous air pollutants for petroleum refineries: catalytic cracking units, catalytic reforming units, and sulfur recovery units. Rescinded IAB 2/15/17, effective 3/22/17.

bv. Emission standards for hazardous air pollutants publicly owned treatment works (POTW). (Part 63, Subpart VVV)

bw. Reserved.

bx. Emission standards for hazardous air pollutants for ferroalloys production: ferromanganese and silicomanganese. Rescinded IAB 3/14/18, effective 4/18/18.

by. and *bz.* Reserved.

ca. Emission standards for hazardous air pollutants: municipal solid waste landfills. This standard applies to existing and new municipal solid waste (MSW) landfills. (Part 63, Subpart AAAA)

cb. No change.

cc. Emission standards for hazardous air pollutants for the manufacturing of nutritional yeast. (Part 63, Subpart CCCC)

cd. Emission standards for hazardous air pollutants for plywood and composite wood products (formerly plywood and particle board manufacturing). These standards apply to new and existing major sources with equipment used to manufacture plywood and composite wood products. This equipment includes dryers, refiners, blenders, formers, presses, board coolers, and other process units associated with the manufacturing process. This also includes coating operations, on-site storage and wastewater

treatment. However, only certain process units (defined in the federal rule) are subject to control or work practice requirements. (Part 63, Subpart DDDD)

ce. Emission standards for hazardous air pollutants for organic liquids distribution (non-gasoline). These standards apply to new and existing major source organic liquids distribution (non-gasoline) operations, which are carried out at storage terminals, refineries, crude oil pipeline stations, and various manufacturing facilities. (Part 63, Subpart EEEE)

cf. Emission standards for hazardous air pollutants for miscellaneous organic chemical manufacturing (MON). These standards establish emission limits and work practice standards for new and existing major sources with miscellaneous organic chemical manufacturing process units, wastewater treatment and conveyance systems, transfer operations, and associated ancillary equipment. (Part 63, Subpart FFFF)

cg. Emission standards for hazardous air pollutants for solvent extraction for vegetable oil production. (Part 63, Subpart GGGG)

ch. Emission standards for hazardous air pollutants for wet-formed fiberglass mat production. This standard applies to wet-formed fiberglass mat production plants that are major sources of hazardous air pollutants. These plants may be stand-alone facilities or located with asphalt roofing and processing facilities. (Part 63, Subpart HHHH)

ci. Emission standards for hazardous air pollutants for surface coating of automobiles and light-duty trucks. These standards apply to new, reconstructed, or existing affected sources, as defined in the standard, that are located at a facility which applies topcoat to new automobile or new light-duty truck bodies or body parts for new automobiles or new light-duty trucks and that is a major source, is located at a major source, or is part of a major source of emissions of hazardous air pollutants. Additional applicability criteria and exemptions from these standards may apply. (Part 63, Subpart IIII)

cj. Emission standards for hazardous air pollutants: paper and other web coating. This standard applies to a facility that is engaged in the coating of paper, plastic film, metallic foil, and other web surfaces located at a major source of hazardous air pollutant (HAP) emissions. (Part 63, Subpart JJJJ)

ck. Emission standards for hazardous air pollutants for surface coating of metal cans. These standards apply to a metal can surface coating operation that uses at least 5,700 liters (1,500 gallons (gal)) of coatings per year and is a major source, is located at a major source, or is part of a major source of hazardous air pollutant emissions. Coating operations located at an area source are not subject to this rule. Additional applicability criteria and exemptions from these standards may apply. (Part 63, Subpart KKKK)

cl. Reserved.

cm. Emission standards for hazardous air pollutants for surface coating of miscellaneous metal parts and products. These standards apply to miscellaneous metal parts and products surface coating facilities that are a major source, are located at a major source, or are part of a major source of hazardous air pollutant emissions. A miscellaneous metal parts and products surface coating facility that is located at an area source is not subject to this standard. Certain sources are exempt as described in the standard. (Part 63, Subpart MMMM)

cn. Emission standards for hazardous air pollutants: surface coating of large appliances. This standard applies to a facility that applies coatings to large appliance parts or products, and is a major source, is located at a major source, or is part of a major source of emissions of hazardous air pollutants (HAPs). The large appliances source category includes facilities that apply coatings to large appliance parts or products. Large appliances include “white goods” such as ovens, refrigerators, freezers, dishwashers, laundry equipment, trash compactors, water heaters, comfort furnaces, electric heat pumps and most HVAC equipment intended for any application. (Part 63, Subpart NNNN)

co. Emission standards for hazardous air pollutants for printing, coating, and dyeing of fabrics and other textiles. These standards apply to new and existing facilities with fabric or other textile coating, printing, slashing, dyeing, or finishing operations, or group of such operations, that are a major source of hazardous air pollutants or are part of a facility that is a major source of hazardous air pollutants. Coating, printing, slashing, dyeing, or finishing operations located at an area source are not subject to

this standard. Several exclusions from this source category are listed in the standard. (Part 63, Subpart OOOO)

cp. Emission standards for surface coating of plastic parts and products. These standards apply to new and existing major sources with equipment used to coat plastic parts and products. The surface coating application process includes drying/curing operations, mixing or thinning operations, and cleaning operations. Coating materials include, but are not limited to, paints, stains, sealers, topcoats, basecoats, primers, inks, and adhesives. (Part 63, Subpart PPPP)

cq. Emission standards for hazardous air pollutants for surface coating of wood building products. These standards establish emission limitations, operating limits, and work practice requirements for wood building products surface coating facilities that use at least 1,100 gallons of coatings per year and are a major source, are located at a major source, or are part of a major source of hazardous air pollutant emissions. Wood building products surface coating facilities located at an area source are not subject to this standard. Several exclusions from this source category are listed in the standard. (Part 63, Subpart QQQQ)

cr. Emission standards for hazardous air pollutants: surface coating of metal furniture. This standard applies to a metal furniture surface coating facility that is a major source, is located at a major source, or is part of a major source of HAP emissions. A metal furniture surface coating facility is one that applies coatings to metal furniture or components of metal furniture. Metal furniture means furniture or components that are constructed either entirely or partially from metal. (Part 63, Subpart RRRR)

cs. Emission standards for hazardous air pollutants: surface coating of metal coil. This standard requires that all new and existing “major” air toxics sources in the metal coil coating industry meet specific emission limits. Metal coil coating is the process of applying a coating (usually protective or decorative) to one or both sides of a continuous strip of sheet metal. Industries using coated metal include: transportation, building products, appliances, can manufacturing, and packaging. Other products using coated metal coil include measuring tapes, ventilation systems for walls and roofs, lighting fixtures, office filing cabinets, cookware, and sign stock material. (Part 63, Subpart SSSS)

ct. Emission standards for hazardous air pollutants for leather finishing operations. This standard applies to a new or existing leather finishing operation that is a major source of hazardous air pollutants (HAPs) emissions or that is located at, or is part of, a major source of HAP emissions. In general, a leather finishing operation is a single process or group of processes used to adjust and improve the physical and aesthetic characteristics of the leather surface through multistage application of a coating comprised of dyes, pigments, film-forming materials, and performance modifiers dissolved or suspended in liquid carriers. (Part 63, Subpart TTTT)

cu. Emission standards for hazardous air pollutants for cellulose products manufacturing. This standard applies to a new or existing cellulose products manufacturing operation that is located at a major source of HAP emissions. Cellulose products manufacturing includes both the miscellaneous viscose processes source category and the cellulose ethers production source category. (Part 63, Subpart UUUU)

cv. Emission standards for hazardous air pollutants for boat manufacturing. (Part 63, Subpart VVVV)

cw. Emission standards for hazardous air pollutants: reinforced plastic composites production. This standard applies to a new or an existing reinforced plastic composites production facility that is located at a major source of HAP emissions. (Part 63, Subpart WWWW)

cx. Emission standards for hazardous air pollutants: rubber tire manufacturing. This standard applies to a rubber tire manufacturing facility that is located at, or is a part of, a major source of hazardous air pollutant (HAP) emissions. Rubber tire manufacturing includes the production of rubber tires and/or the production of components integral to rubber tires, the production of tire cord, and the application of puncture sealant. (Part 63, Subpart XXXX)

cy. Emission standards for hazardous air pollutants for stationary combustion turbines. These standards apply to stationary combustion turbines which are located at a major source of hazardous air pollutant emissions. Several subcategories have been defined within the stationary combustion turbine

source category. Each subcategory has distinct requirements as specified in the standards. These standards do not apply to stationary combustion turbines located at an area source of hazardous air pollutant emissions. (Part 63, Subpart YYYY)

cz. Emission standards for stationary reciprocating internal combustion engines. These standards apply to new and existing major sources and to new and existing area sources with stationary reciprocating internal combustion engines (RICE). For purposes of these standards, stationary RICE means any reciprocating internal combustion engine which uses reciprocating motion to convert heat energy into mechanical work and which is not mobile. (Part 63, Subpart ZZZZ)

da. Emission standards for hazardous air pollutants for lime manufacturing plants. These standards regulate hazardous air pollutant emissions from new and existing lime manufacturing plants that are major sources, are colocated with major sources, or are part of major sources. Additional applicability criteria and exemptions from these standards may apply. (Part 63, Subpart AAAAA)

db. Emission standards for hazardous air pollutants: semiconductor manufacturing. These standards apply to new and existing major sources with semiconductor manufacturing. (Part 63, Subpart BBBB)

dc. Emission standards for hazardous air pollutants for coke ovens: pushing, quenching, and battery stacks. This standard applies to a new or existing coke oven battery at a plant that is a major source of HAP emissions. (Part 63, Subpart CCCCC)

dd. Emission standards for industrial, commercial and institutional boilers and process heaters. These standards apply to new and existing major sources with industrial, commercial or institutional boilers and process heaters. (Part 63, Subpart DDDDD)*

*As of April 15, 2009, the adoption by reference of Part 63, Subpart DDDDD, is rescinded. On July 30, 2007, the United States Court of Appeals for the District of Columbia Circuit issued its mandate vacating 40 CFR Part 63, Subpart DDDDD, in its entirety, and requiring EPA to repromulgate final standards for industrial, commercial or institutional boilers and process heaters at new and existing major sources.

de. Emission standards for hazardous air pollutants for iron and steel foundaries. These standards apply to each new or existing iron and steel foundary that is a major source of hazardous air pollutant emissions. A new affected source is an iron and steel foundary for which construction or reconstruction began after December 23, 2002. An existing affected source is an iron and steel foundary for which construction or reconstruction began on or before December 23, 2002. (Part 63, Subpart EEEEE)

df. Emission standards for hazardous air pollutants for integrated iron and steel manufacturing. These standards apply to affected sources at an integrated iron and steel manufacturing facility that is, or is part of, a major source of hazardous air pollutant emissions. The affected sources are each new or existing sinter plant, blast furnace, and basic oxygen process furnace (BOPF) shop at an integrated iron and steel manufacturing facility that is, or is part of, a major source of hazardous air pollutant emissions. (Part 63, Subpart FFFFF)

dg. Emission standards for hazardous air pollutants: site remediation. These standards apply to new and existing major sources with certain types of site remediation activity on the source's property or on a contiguous property. These standards control hazardous air pollutant (HAP) emissions at major sources where remediation technologies and practices are used at the site to clean up contaminated environmental media (e.g., soil, groundwater, or surface water) or certain stored or disposed materials that pose a reasonable potential threat to contaminate environmental media.

Some site remediations already regulated by rules established under the Comprehensive Environmental Response and Compensation Liability Act (CERCLA) or the Resource Conservation and Recovery Act (RCRA) are not subject to these standards, as specified in Subpart GGGGG. There are also exemptions for short-term remediation and for certain leaking underground storage tanks, as specified in Subpart GGGGG. (Part 63, Subpart GGGGG)

dh. Emission standards for hazardous air pollutants for miscellaneous coating manufacturing. These standards establish emission limits and work practice requirements for new and existing miscellaneous coating manufacturing operations, including, but not limited to, process vessels,

storage tanks, wastewater, transfer operations, equipment leaks, and heat exchange systems. (Part 63, Subpart HHHHH)

di. Emission standards for mercury emissions from mercury cell chlor-alkali plants. These standards apply to the chlorine production source category. This source category contains the mercury cell chlor-alkali plant subcategory and includes all plants engaged in the manufacture of chlorine and caustic in mercury cells. These standards define two affected sources: mercury cell chlor-alkali production facilities and mercury recovery facilities. (Part 63, Subpart IIII)

dj. Emission standards for hazardous air pollutants for brick and structural clay products manufacturing. Rescinded IAB 2/15/17, effective 3/22/17.

dk. Emission standards for hazardous air pollutants for clay ceramics manufacturing. Rescinded IAB 2/15/17, effective 3/22/17.

dl. Emission standards for hazardous air pollutants: asphalt processing and asphalt roofing manufacturing. This standard applies to an existing or new asphalt processing or asphalt roofing manufacturing facility that is a major source of hazardous air pollutants (HAPs) emissions, or is located at, or is part of a major source of HAP emissions. (Part 63, Subpart LLLLL)

dm. Emission standards for hazardous air pollutants: flexible polyurethane foam fabrication operations. This standard applies to a new or existing source at a flexible polyurethane foam fabrication facility. The standard defines two affected sources (units or collections of units to which a given standard or limit applies) corresponding to the two subcategories, loop slitter adhesive use or flame lamination. (Part 63, Subpart MMMMM)

dn. Emission standards for hazardous air pollutants: hydrochloric acid production. This standard applies to a new or existing HCl production facility that produces a liquid HCl product at a concentration of 30 weight percent or greater during its normal operations and is located at, or is part of, a major source of HAP. This does not include HCl production facilities that only occasionally produce liquid HCl product at a concentration of 30 weight percent or greater. (Part 63, Subpart NNNNN)

do. Reserved.

dp. Emission standards for hazardous air pollutants: engine test cells/stands. This standard applies to an engine test cell/stand that is located at a major source of HAP emissions. An engine test cell/stand is any apparatus used for testing uninstalled stationary or uninstalled mobile engines. (Part 63, Subpart PPPPP)

dq. Emission standards for hazardous air pollutants for friction materials manufacturing facilities. This standard applies to a new or existing friction materials manufacturing facility that is (or is part of) a major source of hazardous air pollutants (HAPs) emissions. Friction materials manufacturing facilities produce friction materials for use in brake and clutch assemblies. (Part 63, Subpart QQQQQ)

dr. Emission standards for hazardous air pollutants: taconite iron ore processing. Rescinded IAB 3/18/15, effective 4/22/15.

ds. Emission standards for hazardous air pollutants for refractory products manufacturing. This standard applies to a new or existing refractory products manufacturing facility that is, is located at, or is part of, a major source of hazardous air pollutant (HAP) emissions. (Part 63, Subpart SSSSS)

dt. Emission standards for hazardous air pollutants: primary magnesium refining. Rescinded IAB 3/18/15, effective 4/22/15.

du. Reserved.

dv. Reserved.

dw. Emission standards for hazardous air pollutants for hospital ethylene oxide sterilizer area sources. This standard applies to a hospital that is an area source for hazardous air pollutant emissions and that owns or operates a new or existing ethylene oxide sterilization facility. (Part 63, Subpart WWWW)

dx. Reserved.

dy. Emission standards for hazardous air pollutants for electric arc furnace steelmaking area sources. This standard applies to new or existing electric arc furnace (EAF) steelmaking facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart YYYYY)

dz. Emission standards for hazardous air pollutants for iron and steel foundry area sources. This standard applies to new or existing iron and steel foundries that are area sources for hazardous air pollutant emissions. (Part 63, Subpart ZZZZZ)

ea. Reserved.

eb. Emission standards for hazardous air pollutants for gasoline distribution area sources: bulk terminals, bulk plants and pipeline facilities. This standard applies to new and existing bulk gasoline terminals, pipeline breakout stations, pipeline pumping stations and bulk gasoline plants that are area sources for hazardous air pollutant emissions. (Part 63, Subpart BBBB)

ec. Emission standards for hazardous air pollutants for area sources: gasoline dispensing facilities. This standard applies to new and existing gasoline dispensing facilities (GDF) that are area sources for hazardous air pollutant emissions. The affected equipment includes each gasoline cargo tank during delivery of product to GDF and also includes each storage tank. The equipment used for refueling of motor vehicles is not covered under these standards. (Part 63, Subpart CCCCC)

ed. Reserved.

ee. Reserved.

ef. Reserved.

eg. Reserved.

eh. Emission standards for hazardous air pollutants for area sources: paint stripping and miscellaneous surface coating operations. This standard applies to new or existing area sources of hazardous air pollutant emissions that engage in any of the following activities: (1) paint stripping operations that use methylene chloride (MeCl)-containing paint stripping formulations; (2) spray application of coatings to motor vehicles or mobile equipment; or (3) spray application of coatings to plastic or metal substrate with coatings that contain compounds of chromium (Cr), lead (Pb), manganese (Mn), nickel (Ni) or cadmium (Cd). (Part 63, Subpart HHHHH)

ei. Reserved.

ej. Emission standards for hazardous air pollutants for area sources: industrial, commercial, and institutional boilers. This standard applies to new and existing industrial, commercial and institutional boilers that are area sources for hazardous air pollutant emissions. (Part 63, Subpart JJJJJ)

ek. Reserved.

el. Emission standards for hazardous air pollutants for acrylic and modacrylic fibers production area sources. This standard applies to acrylic and modacrylic fibers production plants that are area sources for hazardous air pollutant emissions. (Part 63, Subpart LLLLL)

em. Emission standards for hazardous air pollutants for carbon black production area sources. This standard applies to carbon black production plants that are area sources for hazardous air pollutants. (Part 63, Subpart MMMMM)

en. Emission standards for hazardous air pollutants for chemical manufacturing of chromium compounds area sources. This standard applies to plants that produce chromium compounds and are area sources for hazardous air pollutants. (Part 63, Subpart NNNNN)

eo. Emission standards for hazardous air pollutants for flexible polyurethane foam production and fabrication area sources. This standard applies to plants that produce flexible polyurethane foam or rebond foam, and plants that fabricate polyurethane foam, that are area sources for hazardous air pollutants. This standard applies to both new and existing area sources. An affected source is existing if construction or reconstruction commenced on or before April 4, 2007. An affected source is new if construction or reconstruction commenced after April 4, 2007. (Part 63, Subpart OOOOO)

ep. Emission standards for hazardous air pollutants for lead acid battery manufacturing area sources. This standard applies to lead acid battery manufacturing plants that are area sources for hazardous air pollutants. Affected sources include all grid casting facilities, paste mixing facilities, three-process operation facilities, lead oxide manufacturing facilities, lead reclamation facilities, and any other lead-emitting operation that is associated with a lead acid battery manufacturing plant. This standard applies to both new and existing area sources. An affected source is existing if construction or reconstruction commenced on or before April 4, 2007. An affected source is new if construction or reconstruction commenced after April 4, 2007. (Part 63, Subpart PTTTT)

eq. Emission standards for hazardous air pollutants for wood preserving area sources. This standard applies to wood preserving operations that are area sources for hazardous air pollutants. This standard applies to both new and existing area sources. An affected source is existing if construction or reconstruction commenced on or before April 4, 2007. An affected source is new if construction or reconstruction commenced after April 4, 2007. (Part 63, Subpart QQQQQQ)

er. Emission standards for hazardous air pollutants for clay ceramics manufacturing area sources. This standard applies to any new or existing clay ceramics manufacturing facility with an atomized glaze spray booth or kiln that fires glazed ceramic ware, that processes more than 50 tons per year of wet clay, and that is an area source for hazardous air pollutant emissions. (Part 63, Subpart RRRRRR)

es. Emission standards for hazardous air pollutants for glass manufacturing area sources. This standard applies to any new or existing glass manufacturing facility that is an area source for hazardous air pollutant emissions and meets the following criteria: (1) manufactures flat glass, glass containers or pressed and blown glass by melting a mixture of raw materials to produce molten glass and form the molten glass into sheets, containers or other shapes; and (2) uses one or more continuous furnaces to produce glass at a rate of at least 50 tons per year and that contains compounds of one or more “glass manufacturing metal HAP,” as defined in 40 CFR 63.11459, as raw materials in a glass manufacturing batch formulation. (Part 63, Subpart SSSSSS)

et. Emissions standards for hazardous air pollutants for secondary nonferrous metals processing area sources. This standard applies to any new or existing secondary nonferrous metals processing facility that is an area source for hazardous air pollutant emissions. This standard applies to all crushing and screening operations at a secondary zinc processing facility and to all furnace melting operations located at any secondary nonferrous metals processing facility. (Part 63, Subpart TTTTTT)

eu. Reserved.

ev. Emission standards for hazardous air pollutants for area sources: chemical manufacturing. This standard applies to chemical manufacturing at new and existing facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart VVVVVV)

ew. Emission standards for hazardous air pollutants for area sources: plating and polishing. This standard applies to plating and polishing activities at new and existing facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart WWWWWW)

ex. Emission standards for hazardous air pollutants for area sources: metal fabrication and finishing. This standard applies to new and existing facilities in which the primary activity or activities at the facility are metal fabrication and finishing and that are area sources for hazardous air pollutant emissions. (Part 63, Subpart XXXXXX)

ey. Reserved.

ez. Emission standards for hazardous air pollutants for area sources: aluminum, copper, and other nonferrous foundries. This standard applies to aluminum, copper, and other nonferrous foundries at new and existing facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart ZZZZZZ)

fa. and *fb.* Reserved.

fc. Emission standards for hazardous air pollutants for area sources: paint and allied products manufacturing. This standard applies to paint and allied products manufacturing at new and existing facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart CCCCCC)

fd. Emission standards for hazardous air pollutants for area sources: prepared feeds manufacturing. This standard applies to prepared feeds manufacturing that produces animal feed products (not including feed for cats or dogs) and uses chromium or manganese compounds at new and existing facilities that are area sources for hazardous air pollutant emissions. (Part 63, Subpart DDDDDDD)

23.1(5) Emission guidelines. The emission guidelines and compliance times for existing sources, as defined in 40 Code of Federal Regulations Part 60 as amended through March 21, 2011, shall apply to the following affected facilities. The corresponding 40 CFR Part 60 subpart designation is in parentheses. A different CFR reference and date for adoption by reference may be included with the subpart designation

indicated in the paragraphs of this subrule. The control of the designated pollutants will be in accordance with federal standards established in Sections 111 and 129 of the Act and 40 CFR Part 60, Subpart B (Adoption and Submittal of State Plans for Designated Facilities), and the applicable subpart(s) for the existing source. Reference test methods (Appendix A), performance specifications (Appendix B), determination of emission rate change (Appendix C), quality assurance procedures (Appendix F) and the general provisions (Subpart A) of 40 CFR Part 60 also apply to the affected facilities.

a. Emission guidelines for municipal solid waste landfills (Subpart Cc). Emission guidelines and compliance times for the control of certain designated pollutants from designated municipal solid waste landfills shall be in accordance with federal standards established in Subparts Cc (Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills) and WWW (Standards of Performance for Municipal Solid Waste Landfills) of 40 CFR Part 60 as amended through April 10, 2000.

(1) Definitions. For the purpose of 23.1(5)“a,” the definitions have the same meaning given to them in the Act and 40 CFR Part 60, Subparts A (General Provisions), B, and WWW, if not defined in this subparagraph.

“Municipal solid waste landfill” or “MSW landfill” means an entire disposal facility in a contiguous geographical space where household waste is placed in or on land. An MSW landfill may also receive other types of RCRA Subtitle D wastes such as commercial solid waste, nonhazardous sludge, and industrial solid waste. Portions of an MSW landfill may be separated by access roads. An MSW landfill may be publicly or privately owned. An MSW landfill may be a new MSW landfill, an existing MSW landfill or a lateral expansion.

(2) Designated facilities.

1. The designated facility to which the emission guidelines apply is each existing MSW landfill for which construction, reconstruction or modification was commenced before May 30, 1991.

2. Physical or operational changes made to an existing MSW landfill solely to comply with an emission guideline are not considered a modification or reconstruction and would not subject an existing MSW landfill to the requirements of 40 CFR Part 60, Subpart WWW (40 CFR 60.750).

3. For MSW landfills subject to rule 567—22.101(455B) only because of applicability to subparagraph 23.1(5)“a”(2), the following apply for obtaining and maintaining a Title V operating permit under 567—22.104(455B):The owner or operator of an MSW landfill with a design capacity less than 2.5 million megagrams or 2.5 million cubic meters is not required to obtain an operating permit for the landfill.

The owner or operator of an MSW landfill with a design capacity greater than or equal to 2.5 million megagrams and 2.5 million cubic meters on or before June 22, 1998, becomes subject to the requirements of 567—subrule 22.105(1) on September 20, 1998. This requires the landfill to submit a Title V permit application to the Air Quality Bureau, Department of Natural Resources, no later than September 20, 1999.

The owner or operator of a closed MSW landfill does not have to maintain an operating permit for the landfill if either of the following conditions are met: the landfill was never subject to the requirement for a control system under subparagraph 23.1(5)“a”(3); or the owner or operator meets the conditions for control system removal specified in 40 CFR § 60.752(b)(2)(v).

(3) Emission guidelines for municipal solid waste landfill emissions.

1. MSW landfill emissions at each MSW landfill meeting the conditions below shall be controlled. A design capacity report must be submitted to the director by November 18, 1997.

The landfill has accepted waste at any time since November 8, 1987, or has additional design capacity available for future waste deposition.

The landfill has a design capacity greater than or equal to 2.5 million megagrams and 2.5 million cubic meters. The landfill may calculate design capacity in either megagrams or cubic meters for comparison with the exemption values. Any density conversions shall be documented and submitted with the report. All calculations used to determine the maximum design capacity must be included in the design capacity report.

The landfill has a nonmethane organic compound (NMOC) emission rate of 50 megagrams per year or more. If the MSW landfill's design capacity exceeds the established thresholds in 23.1(5) "a"(3)"1," the NMOC emission rate calculations must be provided with the design capacity report.

2. The planning and installation of a collection and control system shall meet the conditions provided in 40 CFR 60.752(b)(2) at each MSW landfill meeting the conditions in 23.1(5) "a"(3)"1."

3. MSW landfill emissions collected through the use of control devices must meet the following requirements, except as provided in 40 CFR 60.24 after approval by the Director and U.S. Environmental Protection Agency.

An open flare designed and operated in accordance with the parameters established in 40 CFR 60.18; a control system designed and operated to reduce NMOC by 98 weight percent; or an enclosed combustor designed and operated to reduce the outlet NMOC concentration to 20 parts per million as hexane by volume, dry basis at 3 percent oxygen, or less.

(4) Test methods and procedures. The following must be used:

1. The calculation of the landfill NMOC emission rate listed in 40 CFR 60.754, as applicable, to determine whether the landfill meets the condition in 23.1(5) "a"(3)"3";

2. The operational standards in 40 CFR 60.753;

3. The compliance provisions in 40 CFR 60.755; and

4. The monitoring provisions in 40 CFR 60.756.

(5) Reporting and record-keeping requirements. The record-keeping and reporting provisions listed in 40 CFR 60.757 and 60.758, as applicable, except as provided under 40 CFR 60.24 after approval by the Director and U.S. Environmental Protection Agency, shall be used.

(6) Compliance times.

1. Except as provided for under 23.1(5) "a"(6)"2," planning, awarding of contracts, and installation of MSW landfill air emission collection and control equipment capable of meeting the emission guidelines established under 23.1(5) "a"(3) shall be accomplished within 30 months after the date the initial NMOC emission rate report shows NMOC emissions greater than or equal to 50 megagrams per year.

2. For each existing MSW landfill meeting the conditions in 23.1(5) "a"(3)"1" whose NMOC emission rate is less than 50 megagrams per year on August 20, 1997, installation of collection and control systems capable of meeting emission guidelines in 23.1(5) "a"(3) shall be accomplished within 30 months of the date when the condition in 23.1(5) "a"(3)"1" is met (i.e., the date of the first annual nonmethane organic compounds emission rate which equals or exceeds 50 megagrams per year).

b. Emission guidelines for hospital/medical/infectious waste incinerators (Subpart Ce). This paragraph contains emission guidelines and compliance times for the control of certain designated pollutants from hospital/medical/infectious waste incinerator(s) (HMIWI) in accordance with Subparts Ce and Ec (Standards of Performance for Hospital/Medical/Infectious Waste Incinerators) of 40 CFR Part 60.*

*As of November 24, 2010, the emission guidelines for hospital/medical/infectious waste incinerators (Subpart Ce) are rescinded.

c. Emission guidelines and compliance schedules for existing commercial and industrial solid waste incineration units that commenced construction on or before November 30, 1999. Emission guidelines and compliance schedules for the control of designated pollutants from affected commercial and industrial solid waste incinerators that commenced construction on or before November 30, 1999, shall be in accordance with requirements established in Subpart III of 40 CFR Part 62 and 40 CFR §62.3916 as adopted through August 24, 2004.

d. Emission guidelines for mercury for coal-fired electric utility steam generating units. Rescinded IAB 10/7/09, effective 11/11/09.

e. Emission guidelines and compliance times for existing sewage sludge incineration units (40 CFR Part 62, Subpart LLL). Emission guidelines and compliance times for control of designated pollutants from affected sewage sludge incineration (SSI) units that commenced construction or reconstruction on or before October 14, 2010, shall be in accordance with federal standards established in Subpart LLL of 40 CFR Part 62, as amended through April 29, 2016.

23.1(6) Calculation of emission limitations based upon stack height. This rule sets limits for the maximum stack height credit to be used in ambient air quality modeling for the purpose of setting an emission limitation and calculating the air quality impact of a source. The rule does not limit the actual physical stack height for any source.

For the purpose of this subrule, definitions of “stack,” “a stack in existence,” “dispersion technique,” “nearby” and “excessive concentration” as set forth in 40 CFR §§ 51.100(ff) through (hh), (jj) and (kk) as amended through June 14, 1996, are adopted by reference.

a. “Good engineering practice (GEP) stack height” means the greater of:

- (1) Sixty-five meters, measured from the ground level elevation at the base of the stack; or
- (2) For stacks in existence on January 12, 1979, and for which the owner and operator had obtained all applicable permits or approvals required under 567—Chapter 22 and 40 CFR § 52.21 as amended through June 13, 2007,

$$H_g = 2.5H$$

provided the owner or operator produces evidence that this equation was actually relied on in establishing an emission limitation;

For all other stacks,

$$H_g = H + 1.5L$$

where:

H_g = good engineering practice stack height, measured from the ground level elevation at the base of the stack,

H = height of nearby structure(s) measured from the ground level elevation at the base of the stack,

L = lesser dimension, height or projected width, of nearby structure(s), provided that the department may require the use of a field study or fluid model to verify GEP stack height for the source; or

(3) The height demonstrated by a fluid model or a field study approved by the department, which ensures that the emissions from a stack do not result in excessive concentrations of any air pollutant as a result of atmospheric downwash, wakes, or eddy effects created by the source itself, nearby structures or nearby terrain features. Public notification of the availability of such study and opportunity for public hearing are required prior to approval by the department.

b. The degree of emission limitation required for control of any air contaminant under this chapter shall not be affected in any manner by:

- (1) The consideration of that portion of a stack which exceeds GEP stack height; or
- (2) Varying the rate of emission of a pollutant according to atmospheric conditions or ambient concentrations of that pollutant; or
- (3) Increasing final exhaust gas plume rise by manipulating source process parameters, exhaust gas parameters, stack parameters, or combined exhaust gases from several existing stacks into one stack; or other selective handling of exhaust gas streams so as to increase gas plume rise.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 7565B, IAB 2/11/09, effective 3/18/09; ARC 7623B, IAB 3/11/09, effective 4/15/09; ARC 8216B, IAB 10/7/09, effective 11/11/09; ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 9154B, IAB 10/20/10, effective 11/24/10 (See Delay note at end of chapter) (See Rescission note at end of chapter); ARC 0329C, IAB 9/19/12, effective 10/24/12; ARC 1014C, IAB 9/18/13, effective 10/23/13; ARC 1561C, IAB 8/6/14, effective 9/10/14; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—23.2(455B) Open burning.

23.2(1) Prohibition. No person shall allow, cause or permit open burning of combustible materials, except as provided in 23.2(2) and 23.2(3).

23.2(2) Variances from rules. Any person wishing to conduct open burning of materials not exempted in 23.2(3) may make application for a variance as specified in 567—subrule 21.2(1). In addition to requiring the information specified under 567—subrule 21.2(1), the director may require any person applying for a variance from the open burning rules to submit adequate documentation to allow the director to assess whether granting the variance will hinder attainment or maintenance of a National Ambient Air Quality Standard (NAAQS).

23.2(3) Exemptions. The open burning exemptions specified in this subrule shall not be construed as exemptions from any other applicable environmental regulations. In particular, the exemptions contained in this subrule do not absolve any person from compliance with the rules for solid waste disposal, including ash disposal, and solid waste permitting contained in 567—Chapters 100 through 130 or the rules for storm water runoff and storm water permitting contained in 567—Chapters 60 and 64. The following shall be permitted unless prohibited by local ordinances or regulations.

a. Disaster rubbish. The open burning of rubbish, including landscape waste, for the duration of the community disaster period in cases where an officially declared emergency condition exists. Burning of any structures or demolished structures shall be conducted in accordance with 40 CFR Section 61.145 as amended through January 16, 1991, which is the “Standard for Demolition and Renovation” of the asbestos National Emission Standard for Hazardous Air Pollutants.

b. Trees and tree trimmings. The open burning of trees and tree trimmings not originated on the premises provided that the burning site is operated by a local governmental entity, the burning site is fenced and access is controlled, burning is conducted on a regularly scheduled basis and is supervised at all times, burning is conducted only when weather conditions are favorable with respect to surrounding property, and the burning site is limited to areas at least one-quarter mile from any inhabited building unless a written waiver in the form of an affidavit is submitted by the owner of the building to the department and to the local governmental entity prior to the first instance of open burning at the site which occurs after November 13, 1996. The written waiver shall become effective only upon recording in the office of the recorder of deeds of the county in which the inhabited building is located. However, when the open burning of trees and tree trimmings causes air pollution as defined in Iowa Code section 455B.131(3), the department may take appropriate action to secure relocation of the burning operation. Rubber tires shall not be used to ignite trees and tree trimmings.

This exemption shall not apply within the area classified as the PM10 (inhalable) particulate Group II area of Mason City. This Group II area is described as follows: the area in Cerro Gordo County, Iowa, in Lincoln Township including Sections 13, 24 and 25; in Lime Creek Township including Sections 18, 19, 20, 21, 27, 28, 29, 30, 31, 32, 33, 34 and 35; in Mason Township the W ½ of Section 1, Sections 2, 3, 4, 5, 8, 9, the N ½ of Section 11, the NW ¼ of Section 12, the N ½ of Section 16, the N ½ of Section 17 and the portions of Sections 10 and 15 north and west of the line from U.S. Highway 18 south on Kentucky Avenue to 9th Street SE; thence west on 9th Street SE to the Minneapolis and St. Louis railroad tracks; thence south on Minneapolis and St. Louis railroad tracks to 19th Street SE; thence west on 19th Street SE to the section line between Sections 15 and 16.

c. Flare stacks. The open burning or flaring of waste gases, providing such open burning or flaring is conducted in compliance with 23.3(2) “d” and 23.3(3) “e.”

d. Landscape waste. The disposal by open burning of landscape waste originating on the premises. However, the burning of landscape waste produced in clearing, grubbing and construction operations shall be limited to areas located at least one-fourth mile from any building inhabited by other than the landowner or tenant conducting the open burning. Rubber tires shall not be used to ignite landscape waste.

e. Recreational fires. Open fires for cooking, heating, recreation and ceremonies, provided they comply with 23.3(2) “d.” Burning rubber tires is prohibited from this activity.

f. Residential waste. Backyard burning of residential waste at dwellings of four-family units or less. The adoption of more restrictive ordinances or regulations of a governing body of the political subdivision, relating to control of backyard burning, shall not be precluded by these rules.

g. Training fires. For purposes of subrule 23.2(3), a “training fire” is a fire set for the purposes of conducting bona fide training of public or industrial employees in firefighting methods. For purposes of this paragraph, “bona fide training” means training that is conducted according to the National Fire Protection Association 1403 Standard of Live Fire Training Evolutions (2002 Edition) or a comparable training fire standard. A training fire may be conducted, provided that all of the following conditions are met:

- (1) A training fire on a building is conducted with the building structurally intact.
- (2) The training fire does not include the controlled burn of a demolished building.

(3) If the training fire is to be conducted on a building, written notification is provided to the department on DNR Form 542-8010, Notification of an Iowa Training Fire-Demolition or a Controlled Burn of a Demolished Building, and is postmarked or delivered to the director at least ten working days before such action commences.

(4) Notification shall be made in accordance with 40 CFR Section 61.145, "Standard for Demolition and Renovation" of the asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), as amended through January 16, 1991.

(5) All asbestos-containing materials shall be removed prior to the training fire.

(6) Asphalt roofing may be burned in the training fire only if notification to the director contains testing results indicating that none of the layers of asphalt roofing contain asbestos. During each calendar year, each fire department may conduct no more than two training fires on buildings where asphalt roofing has not been removed, provided that for each of those training fires the asphalt roofing material present has been tested to ensure that it does not contain asbestos. Each fire department's limit on the burning of asphalt roofing shall include both training fires and the controlled burning of a demolished building, as specified in 23.2(3)"j."

(7) Rubber tires shall not be burned during a training fire.

h. Paper or plastic pesticide containers and seed corn bags. The disposal by open burning of paper or plastic pesticide containers (except those formerly containing organic forms of beryllium, selenium, mercury, lead, cadmium or arsenic) and seed corn bags resulting from farming activities occurring on the premises. Such open burning shall be limited to areas located at least one-fourth mile from any building inhabited by other than the landowner or tenant conducting the open burning, livestock area, wildlife area, or water source. The amount of paper or plastic pesticide containers and seed corn bags that can be disposed of by open burning shall not exceed one day's accumulation or 50 pounds, whichever is less. However, when the burning of paper or plastic pesticide containers or seed corn bags causes a nuisance, the director may take action to secure relocation of the burning operation. Since the concentration levels of pesticide combustion products near the fire may be hazardous, the person conducting the open burning should take precautions to avoid inhalation of the pesticide combustion products.

i. Agricultural structures. The open burning of agricultural structures, provided that the open burning occurs on the premises and, for agricultural structures located within a city or town, at least one-fourth mile from any building inhabited by a person other than the landowner, a tenant, or an employee of the landowner or tenant conducting the open burning unless a written waiver in the form of an affidavit is submitted by the owner of the building to the department prior to the open burning; all chemicals and asphalt roofing are removed; burning is conducted only when weather conditions are favorable with respect to surrounding property; and permission from the local fire chief is secured in advance of the burning. Rubber tires shall not be used to ignite agricultural structures. The asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), as amended through January 16, 1991, requires the burning of agricultural structures to be conducted in accordance with 40 CFR Section 61.145, "Standard for Demolition and Renovation."

For the purposes of this subrule, "agricultural structures" means barns, machine sheds, storage cribs, animal confinement buildings, and homes located on the premises and used in conjunction with crop production, livestock or poultry raising and feeding operations. "Agricultural structures," for asbestos NESHAP purposes, includes all of the above, with the exception of a single residential structure on the premises having four or fewer dwelling units, which has been used only for residential purposes.

j. Controlled burning of a demolished building. A city, as "city" is defined in Iowa Code section 362.2(4), with approval of its council, as "council" is defined in Iowa Code section 362.2(8), may conduct a controlled burn of a demolished building. A city is the only party that may conduct such a burn and is responsible for ensuring that all of the following conditions are met:

(1) *Prohibition.* The controlled burning of a demolished building is prohibited within the city limits of Cedar Rapids, Marion, Hiawatha, Council Bluffs, Carter Lake, Des Moines, West Des Moines, Clive, Windsor Heights, Urbandale, Pleasant Hill, Buffalo, Davenport, Mason City or any other area where area-specific state implementation plans require the control of particulate matter.

(2) *Notification requirements.* For each building proposed to be burned, the city fire department or a city official, on behalf of the city, shall submit to the department a completed notification postmarked at least 10 working days prior to commencing demolition and at least 30 days before the proposed controlled burn commences. Documentation of city council approval shall be submitted with the notification. Information required to be provided shall include: the exact location of the burn site; the approximate distance to the nearest neighboring residence or business; the method used by the city to notify nearby residents of the proposed burn; an explanation of why alternative methods of demolition debris management are not being used; and information required by 40 CFR Section 61.145, "Standard for Demolition and Renovation" of the asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), as amended through January 16, 1991. Notification shall be provided on DNR Form 542-8010, Notification of an Iowa Training Fire-Demolition or a Controlled Burn of a Demolished Building. For burns conducted outside the city limits, the city shall send to the chairperson of the applicable county board a copy of the completed DNR notification form 542-8010 and documentation of city council approval. Notification to the county board shall be postmarked, faxed or sent by electronic mail at least 30 days before the proposed controlled burn commences.

(3) *Asbestos removal requirements.* All asbestos-containing materials shall be removed before the building to be burned is demolished. The department may require proof that any applicable inspection, notification, removal and demolition occurred, or will occur, in accordance with 40 CFR Section 61.145, "Standard for Demolition and Renovation" of the asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), as amended through January 16, 1991.

(4) *Requirements for asphalt roofing.* During each calendar year, each city shall conduct no more than two controlled burns of a demolished building in which asphalt roofing has not been removed, provided that for each controlled burn of a demolished building the asphalt roofing material present has been tested to ensure that it does not contain asbestos. Each city's limit on the burning of asphalt roofing shall include both the controlled burning of a demolished building and training fires, as specified in paragraph 23.2(3)"g."

(5) *Building size limit.* For each proposed controlled burn located within the city limits, more than one demolished building may be included in the burn, provided that the sum total of all building material to be burned at a designated site does not exceed 1700 square feet in size. For a controlled burn site located outside the city limits, the sum total of all building material to be burned, per day, may not exceed 1700 square feet in size. For purposes of this subparagraph, "square feet" includes both finished and unfinished basements and excludes unfinished attics, carports, attached garages, and porches that are not protected from weather.

(6) *Time of day requirements.* The controlled burning of a demolished building may be conducted only between the hours of 6 a.m. and 6 p.m. and only when weather conditions are favorable with respect to surrounding property. The city shall adequately schedule and sufficiently control the burn to ensure that burning is completed by 6 p.m.

(7) *Prohibited materials.* Rubber tires, chemicals, furniture, carpeting, household appliances, vinyl products (such as flooring or siding), trade waste, garbage, rubbish, landscape waste, residential waste, and other nonstructural materials shall not be burned.

(8) *Limits on the number and location of burns.* For burns conducted within the city limits, each city may undertake no more than one controlled burn of demolished building material in every 0.6-mile-radius circle during each calendar year. For burn sites established outside the city limits, each city shall undertake no more than one controlled burn of demolished building material per day. A burn site outside the city limits must be located at least 0.6 of a mile from any building inhabited by a person, as "person" is defined in Iowa Code section 362.2(17).

(9) *Requirements for burn access and supervision.* The city shall control access to all demolished building burn sites. Representatives of the city who are city employees or who are hired by the city shall supervise the burning of demolished building material at all times.

(10) *Record-keeping requirements.* The city shall retain at least one copy of all notifications and supplementary information required to be sent to the department under subparagraph (2). Additionally, the city shall maintain a map of the exact location of each burn site, and supporting documentation

showing the date of each demolished building burn and the square feet of building material burned on each date. All maps, notifications and associated records shall be maintained by the city clerk, as “clerk” is defined in Iowa Code section 362.2(7), for a period of at least three years and shall be made available for inspection by the department upon request.

(11) *Variance from this paragraph.* In accordance with 567—subrules 21.2(1) and 23.2(2), a city may apply for a variance from the specific conditions for controlled burning of a demolished building and may request that the director conduct a review of the ambient air impacts of the request. The director shall approve or deny the request in accordance with 567—subrule 21.2(4).

(12) *Compliance with other applicable environmental regulations.* Compliance with the exemption requirements in this paragraph shall not absolve a city of the responsibility to comply with any other applicable environmental regulations. In particular, a city conducting a controlled burn of a demolished building shall comply with all applicable solid waste disposal, including ash disposal, and solid waste permitting rules contained in 567—Chapters 100 through 130, as well as all applicable storm water discharge and storm water permitting rules contained in 567—Chapters 60 and 64.

23.2(4) Unavailability of exemptions in certain areas. Notwithstanding 23.2(2) and 23.2(3) “b,” “d,” “f,” and “i,” no person shall allow, cause or permit the open burning of trees or tree trimmings, residential or landscape waste or agricultural structures in the cities of: Cedar Rapids, Marion, Hiawatha, Council Bluffs, Carter Lake, Des Moines, West Des Moines, Clive, Windsor Heights, Urbandale, and Pleasant Hill.

This rule is intended to implement Iowa Code section 455B.133.

567—23.3(455B) Specific contaminants.

23.3(1) General. The emission standards contained in this rule shall apply to each source operation unless a performance standard for the process is specified in subrule 23.1(2), in which case the performance standard shall apply.

23.3(2) Particulate matter. No person shall cause or allow the emission of particulate matter from any source in excess of the emission standards specified in this chapter, except as provided in 567—Chapter 24.

a. General emission rate.

(1) For sources constructed, modified or reconstructed on or after July 21, 1999, the emission of particulate matter from any process shall not exceed an emission standard of 0.1 grain per dry standard cubic foot (dscf) of exhaust gas, except as provided in 567—21.2(455B), 567—23.1(455B), 567—23.4(455B), and 567—Chapter 24.

(2) For sources constructed, modified or reconstructed prior to July 21, 1999, the emission of particulate matter from any process shall not exceed the amount determined from Table I, or amount specified in a permit if based on an emission standard of 0.1 grain per standard cubic foot of exhaust gas, or established from standards provided in 567—23.1(455B) and 567—23.4(455B).

TABLE I
ALLOWABLE RATE OF EMISSION BASED ON PROCESS WEIGHT RATE*

Process Weight Rate		Emission Rate	Process Weight Rate		Emission Rate
Lb/Hr	Tons/Hr	Lb/Hr	Lb/Hr	Tons/Hr	Lb/Hr
100	0.05	0.55	16,000	8.00	16.5
200	0.10	0.88	18,000	9.00	17.9
400	0.20	1.40	20,000	10.00	19.2
600	0.30	1.83	30,000	15.00	25.2
800	0.40	2.22	40,000	20.00	30.5
1,000	0.50	2.58	50,000	25.00	35.4
1,500	0.75	3.38	60,000	30.00	40.0
2,000	1.00	4.10	70,000	35.00	41.3

Process Weight Rate		Emission Rate	Process Weight Rate		Emission Rate
Lb/Hr	Tons/Hr	Lb/Hr	Lb/Hr	Tons/Hr	Lb/Hr
2,500	1.25	4.76	80,000	40.00	42.5
3,000	1.50	5.38	90,000	45.00	43.6
3,500	1.75	5.96	100,000	50.00	44.6
4,000	2.00	6.52	120,000	60.00	46.3
5,000	2.50	7.58	140,000	70.00	47.8
6,000	3.00	8.56	160,000	80.00	49.0
7,000	3.50	9.49	200,000	100.00	51.2
8,000	4.00	10.4	1,000,000	500.00	69.0
9,000	4.50	11.2	2,000,000	1,000.00	77.6
10,000	5.00	12.0	6,000,000	3,000.00	92.7
12,000	6.00	13.6			

*Interpolation of the data in this table for process weight rates up to 60,000 lb/hr shall be accomplished by the use of the equation

$$E=4.10 P^{0.67},$$

and interpolation and extrapolation of the data for process weight rates in excess of 60,000 lb/hr shall be accomplished by use of the equation

$$E=55.0 P^{0.11}-40,$$

where E = rate of emission in lb/hr, and

P = process weight in tons/hr

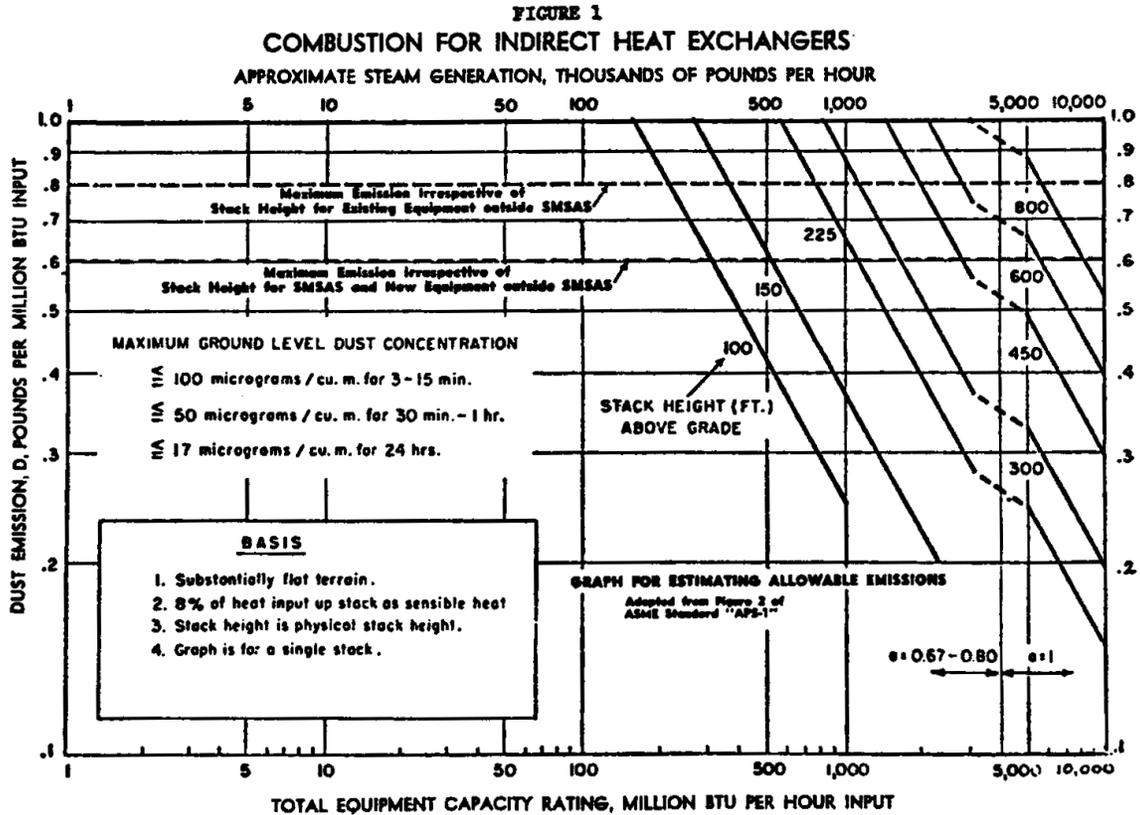
b. Combustion for indirect heating. Emissions of particulate matter from the combustion of fuel for indirect heating or for power generation shall be limited by the ASME Standard APS-1, Second Edition, November, 1968, "Recommended Guide for the Control of Dust Emission—Combustion for Indirect Heat Exchangers." For the purpose of this paragraph, the allowable emissions shall be calculated from equation (15) in that standard, with $Comax^2=50$ micrograms per cubic meter. Allowable emissions from a single stack may be estimated from Figure 1. The maximum ground level dust concentrations designated are above the background level. For plants with 4,000 million Btu/hour input or more, the "a" factor shall be 1.0. In plants with less than 4,000 million Btu/hour input, appropriate "a" factors, less than 1.0, shall be applied. Pertinent correction factors, as specified in the standard, shall be applied for installations with multiple stacks. However, for fuel-burning units in operation on January 13, 1976, the maximum allowable emissions calculated under APS-1 for the facility's equipment configuration on January 13, 1976, shall not be increased even if the changes in the equipment or stack configuration would otherwise allow a recalculation and a higher maximum allowable emission under APS-1.

(1) Outside any standard metropolitan statistical area, the maximum allowable emissions from each stack, irrespective of stack height, shall be 0.8 pounds of particulates per million Btu input.

(2) Inside any standard metropolitan statistical area, the maximum allowable emission from each stack, irrespective of stack height, shall be 0.6 pounds of particulates per million Btu input.

(3) For a new fossil fuel-fired steam generating unit of more than 250 million Btu per hour heat input, 23.1(2) "a" shall apply. For a new unit of between 150 million and 250 million (inclusive) Btu per hour heat input, the maximum allowable emissions from such new unit shall be 0.2 pounds of particulates per million Btu of heat input. For a new unit of less than 150 million Btu per hour heat input, the maximum allowable emissions from such new unit shall be 0.6 pounds of particulates per million Btu of heat input.

(4) Measurements of emissions from a particulate source will be made in accordance with the provisions of 567—Chapter 25.



(5) For fuel-burning sources in operation prior to July 29, 1977, which are not subject to 23.1(2) and which significantly impact a primary or secondary particulate standard nonattainment area, the emission limitations specified in this subparagraph apply. A significant impact shall be equal to or exceeding 5 micrograms of particulate matter per cubic meter of air (24-hour average) or 1 microgram of particulate matter per cubic meter of air (annual average) determined by an EPA approved single source dispersion model using allowable emission rates and five-year worst case meteorological conditions. In the case where two or more boilers discharge into a common stack, the applicable stack emission limitation shall be based upon the heat input of the largest operating boiler. The plantwide allowable emission limitation shall be the weighted average of the allowable emission limitations for each stack or the applicable APS-1 plantwide standard as determined under paragraph 23.3(2) "b," whichever is more stringent.

The maximum allowable emission rate for a single stack with a total heat input capacity less than 250 million Btu per hour shall be 0.60 pound of particulate matter per million Btu heat input; the maximum allowable emission rate for a single stack with a total heat input capacity greater than or equal to 250 million Btu per hour and less than 500 million Btu per hour shall be 0.40 pound of particulate matter per million Btu heat input; the maximum allowable emission rate for a single stack with a total heat input capacity greater than or equal to 500 million Btu per hour shall be 0.30 pound of particulate matter per million Btu heat input; except that the maximum allowable emission rate for the stack serving Unit #1 of Iowa Public Service at Port Neal shall be 0.50 pound of particulate matter per million Btu heat input.

All sources regulated under this subparagraph shall demonstrate compliance by October 1, 1981; however, a source is considered to be in compliance with this subparagraph if by October 1, 1981, it is on a compliance schedule to be completed as expeditiously as possible, but no later than December 31, 1982.

c. Fugitive dust.

(1) Attainment and unclassified areas. A person shall take reasonable precautions to prevent particulate matter from becoming airborne in quantities sufficient to cause a nuisance as defined in Iowa Code section 657.1 when the person allows, causes or permits any materials to be handled, transported

or stored or a building, its appurtenances or a construction haul road to be used, constructed, altered, repaired or demolished, with the exception of farming operations or dust generated by ordinary travel on unpaved roads. Ordinary travel includes routine traffic and road maintenance activities such as scarifying, compacting, transporting road maintenance surfacing material, and scraping of the unpaved public road surface. All persons, with the above exceptions, shall take reasonable precautions to prevent the discharge of visible emissions of fugitive dusts beyond the lot line of the property on which the emissions originate. The public highway authority shall be responsible for taking corrective action in those cases where said authority has received complaints of or has actual knowledge of dust conditions which require abatement pursuant to this subrule. Reasonable precautions may include, but not be limited to, the following procedures.

1. Use, where practical, of water or chemicals for control of dusts in the demolition of existing buildings or structures, construction operations, the grading of roads or the clearing of land.
2. Application of suitable materials, such as but not limited to asphalt, oil, water or chemicals on unpaved roads, material stockpiles, race tracks and other surfaces which can give rise to airborne dusts.
3. Installation and use of containment or control equipment, to enclose or otherwise limit the emissions resulting from the handling and transfer of dusty materials, such as but not limited to grain, fertilizer or limestone.
4. Covering, at all times when in motion, open-bodied vehicles transporting materials likely to give rise to airborne dusts.
5. Prompt removal of earth or other material from paved streets or to which earth or other material has been transported by trucking or earth-moving equipment, erosion by water or other means.
6. Reducing the speed of vehicles traveling over on-property surfaces as necessary to minimize the generation of airborne dusts.

(2) *Nonattainment areas.* Subparagraph (1) notwithstanding, no person shall allow, cause or permit any visible emission of fugitive dust in a nonattainment area for particulate matter to go beyond the lot line of the property on which a traditional source is located without taking reasonable precautions to prevent emission. Traditional source means a source category for which a particulate emission standard has been established in 23.1(2), 23.3(2) "a," 23.3(2) "b" or 567—23.4(455B) and includes a quarry operation, haul road or parking lot associated with a traditional source. This paragraph does not modify the emission standard stated in 23.1(2), 23.3(2) "a," 23.3(2) "b" or 567—23.4(455B), but rather establishes a separate requirement for fugitive dust from such sources. For guidance on the types of controls which may constitute reasonable precautions, see "Identification of Techniques for the Control of Industrial Fugitive Dust Emissions," [available from the department] adopted by the commission on May 19, 1981.

(3) *Reclassified areas.* Reasonable precautions implemented pursuant to the nonattainment area provisions of subparagraph (2) shall remain in effect if the nonattainment area is redesignated to either attainment or unclassified after March 6, 1980.

d. Visible emissions. No person shall allow, cause or permit the emission of visible air contaminants into the atmosphere from any equipment, internal combustion engine, premise fire, open fire or stack, equal to or in excess of 40 percent opacity or that level specified in a construction permit, except as provided below and in 567—Chapter 24.

(1) *Residential heating equipment.* Residential heating equipment serving dwellings of four family units or less is exempt.

(2) *Gasoline-powered vehicles.* No person shall allow, cause or permit the emission of visible air contaminants from gasoline-powered motor vehicles for longer than five consecutive seconds.

(3) *Diesel-powered vehicles.* No person shall allow, cause or permit the emission of visible air contaminants from diesel-powered motor vehicles in excess of 40 percent opacity, for longer than five consecutive seconds.

(4) *Diesel-powered locomotives.* No person shall allow, cause or permit the emission of visible air contaminants from diesel-powered locomotives in excess of 40 percent opacity, except for a maximum period of 40 consecutive seconds during acceleration under load, or for a period of four consecutive minutes when a locomotive is loaded after a period of idling.

(5) *Startup and testing.* Initial start and warmup of a cold engine, the testing of an engine for trouble, diagnosis or repair, or engine research and development activities, is exempt.

(6) *Uncombined water.* The provisions of this paragraph shall apply to any emission which would be in violation of these provisions except for the presence of uncombined water, such as condensed water vapor.

23.3(3) Sulfur compounds. The provisions of this subrule shall apply to any installation from which sulfur compounds are emitted into the atmosphere.

a. Sulfur dioxide from use of solid fuels.

(1) No person shall allow, cause, or permit the emission of sulfur dioxide into the atmosphere from an existing solid fuel-burning unit, (i.e., a unit which was in operation or for which components had been purchased, or which was under construction prior to September 23, 1970), in an amount greater than 6 pounds, replicated maximum three-hour average, per million Btu of heat input if such unit is located within the following counties: Black Hawk, Clinton, Des Moines, Dubuque, Jackson, Lee, Linn, Lousia, Muscatine and Scott.

(2) No person shall allow, cause, or permit the emission of sulfur dioxide into the atmosphere from an existing solid fuel-burning unit, (i.e., a unit which was in operation or for which components had been purchased, or which was under construction prior to September 23, 1970), in an amount greater than 5 pounds, replicated maximum three-hour average, per million Btu of heat input if such unit is located within the remaining 89 counties of the state not listed in subparagraph 23.3(3) "a"(1).

(3) No person shall allow, cause, or permit the emission of sulfur dioxide into the atmosphere from any new solid fuel-burning unit (i.e., a unit which was not in operation or for which components had not been purchased, or which was not under construction prior to September 23, 1970) which has a capacity of 250 million Btu or less per hour heat input, in an amount greater than 6 pounds, replicated maximum three-hour average, per million Btu of heat input.

(4) Subparagraphs (1) through (3) notwithstanding, a fossil fuel-fired steam generator to which 23.1(2) "a," 23.1(2) "z" or 23.1(2) "ccc" applies shall comply with 23.1(2) "a," 23.1(2) "z" or 23.1(2) "ccc," respectively.

b. Sulfur dioxide from use of liquid fuels.

(1) No person shall allow, cause, or permit the combustion of number 1 or number 2 fuel oil exceeding a sulfur content of 0.5 percent by weight.

(2) No person shall allow, cause, or permit the emission of sulfur dioxide into the atmosphere in an amount greater than 2.5 pounds of sulfur dioxide, replicated maximum three-hour average, per million Btu of heat input from a liquid fuel-burning unit.

(3) Notwithstanding this paragraph, a fossil fuel-fired steam generator to which 23.1(2) "a," 23.1(2) "z" or 23.1(2) "ccc" applies shall comply with 23.1(2) "a," 23.1(2) "z" or 23.1(2) "ccc."

c. Sulfur dioxide from sulfuric acid manufacture. After January 1, 1975, no person shall allow, cause or permit the emission of sulfur dioxide from an existing sulfuric acid manufacturing plant in excess of 30 pounds of sulfur dioxide, maximum three-hour average, per ton of product calculated as 100 percent sulfuric acid.

d. Acid mist from sulfuric acid manufacture. After January 1, 1974, no person shall allow, cause or permit the emission of acid mist calculated as sulfuric acid from an existing sulfuric acid manufacturing plant in excess of 0.5 pounds, maximum three-hour average, per ton of product calculated as 100 percent sulfuric acid.

e. Other processes capable of emitting sulfur dioxide. After January 1, 1974, no person shall allow, cause or permit the emission of sulfur dioxide from any process, other than sulfuric acid manufacture, in excess of 500 parts per million, based on volume. This paragraph shall not apply to devices which have been installed for air pollution abatement purposes where it is demonstrated by the owner of the source that the ambient air quality standards are not being exceeded.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 2949C, IAB 2/15/17, effective 3/22/17]

567—23.4(455B) Specific processes.

23.4(1) General. The provisions of this rule shall not apply to those facilities for which performance standards are specified in 23.1(2). The emission standards specified in this rule shall apply and those specified in 23.3(2) “a” and 23.3(2) “b” shall not apply to each process of the types listed in the following subrules, except as provided below.

EXCEPTION: Whenever the director determines that a process complying with the emission standard prescribed in this section is causing or will cause air pollution in a specific area of the state, the specific emission standard may be suspended and compliance with the provisions of 567—23.3(455B) may be required in such instance.

23.4(2) Asphalt batching plants. No person shall cause, allow or permit the operation of an asphalt batching plant in a manner such that the particulate matter discharged to the atmosphere exceeds 0.15 grain per standard cubic foot of exhaust gas.

23.4(3) Cement kilns. Cement kilns shall be equipped with air pollution control devices to reduce the particulate matter in the gas discharged to the atmosphere to no more than 0.3 percent of the particulate matter entering the air pollution control device. Regardless of the degree of efficiency of the air pollution control device, particulate matter discharged from such kilns shall not exceed 0.1 grain per standard cubic foot of exhaust gas.

23.4(4) Cupolas for metallurgical melting. The emissions of particulate matter from all new foundry cupolas, and from all existing foundry cupolas with a process weight rate in excess of 20,000 pounds per hour, shall not exceed the amount specified in paragraph 23.3(2) “a,” except as provided in 567—Chapter 24.

The emissions of particulate matter from all existing foundry cupolas with a process weight rate less than or equal to 20,000 pounds per hour shall not exceed the amount determined from Table II of these rules, except as provided in 567—Chapter 24.

TABLE II
ALLOWABLE EMISSIONS FROM
EXISTING SMALL FOUNDRY CUPOLAS

Process weight rate (lb/hr)	Allowable emission (lb/hr)
1,000	3.05
2,000	4.70
3,000	6.35
4,000	8.00
5,000	9.58
6,000	11.30
7,000	12.90
8,000	14.30
9,000	15.50
10,000	16.65
12,000	18.70
16,000	21.60
18,000	23.40
20,000	25.10

23.4(5) Electric furnaces for metallurgical melting. The emissions of particulate matter to the atmosphere from electric furnaces used for metallurgical melting shall not exceed 0.1 grain per standard cubic foot of exhaust gas.

23.4(6) Sand handling and surface finishing operations in metal processing. This subrule shall apply to any new foundry or metal processing operation not properly termed a combustion, melting, baking or pouring operation. For purposes of this subrule, a new process is any process which has not started operation, or the construction of which has not been commenced, or the components of which have not been ordered or contracts for the construction of which have not been let on August 1, 1977. No person shall allow, cause or permit the operation of any equipment designed for sand shakeout, mulling, molding, cleaning, preparation, reclamation or rejuvenation or any equipment for abrasive cleaning, shot blasting, grinding, cutting, sawing or buffing in such a manner that particulate matter discharged from any stack exceeds 0.05 grains per dry standard cubic foot of exhaust gas, regardless of the types and number of operations that discharge from the stack.

23.4(7) Grain handling and processing plants. The owner or operator of equipment at a permanent installation for the handling or processing of grain, grain products and grain by-products shall not cause, allow or permit the particulate matter discharged to the atmosphere to exceed 0.1 grain per dry standard cubic foot of exhaust gas, except as follows:

a. The particulate matter discharged to the atmosphere from a grain bin vent at a country grain elevator, as “country grain elevator” is defined in 567—subrule 22.10(1), shall not exceed 1.0 grain per dry standard cubic foot of exhaust gas.

b. The particulate matter discharged to the atmosphere from a grain bin vent that was constructed, modified or reconstructed before March 31, 2008, at a country grain terminal elevator, as “country grain terminal elevator” is defined in 567—subrule 22.10(1), or at a grain terminal elevator, as “grain terminal elevator” is defined in 567—subrule 22.10(1), shall not exceed 1.0 grain per dry standard cubic foot of exhaust gas.

c. The particulate matter discharged to the atmosphere from a grain bin vent that is constructed or reconstructed on or after March 31, 2008, at a country grain terminal elevator, as “country grain terminal elevator” is defined in 567—subrule 22.10(1), or at a grain terminal elevator, as “grain terminal elevator” is defined in 567—subrule 22.10(1), shall not exceed 0.1 grain per dry standard cubic foot of exhaust gas.

23.4(8) Lime kilns. No person shall cause, allow or permit the operation of a kiln for the processing of limestone such that the particulate matter in the gas discharged to the atmosphere exceeds 0.1 grain per standard cubic foot of exhaust gas.

23.4(9) Meat smokehouses. No person shall cause, allow or permit the operation of a meat smokehouse or a group of meat smokehouses, which consume more than ten pounds of wood, sawdust or other material per hour such that the particulate matter discharged to the atmosphere exceeds 0.2 grain per standard cubic foot of exhaust gas.

23.4(10) Phosphate processing plants.

a. Phosphoric acid manufacture. No person shall allow, cause or permit the operation of equipment for the manufacture of phosphoric acid that was in existence on October 22, 1974, in a manner that produces more than 0.04 pound of fluoride per ton of phosphorous pentoxide or equivalent input.

b. Diammonium phosphate manufacture. No person shall allow, cause or permit the operation of equipment for the manufacture of diammonium phosphate that was in existence on October 22, 1974, in a manner that produces more than 0.15 pound of fluoride per ton of phosphorous pentoxide or equivalent input.

c. Nitrophosphate manufacture. No person shall allow, cause or permit the operation of equipment for the manufacture of nitrophosphate in a manner that produces more than 0.06 pound of fluoride per ton of phosphorus pentoxide or equivalent input.

d. No person shall allow, cause or permit the operation of equipment for the processing of phosphate ore, rock or other phosphatic material (other than equipment used for the manufacture of phosphoric acid, diammonium phosphate or nitrophosphate) in a manner that the unit emissions of fluoride exceed 0.4 pound of fluoride per ton of phosphorous pentoxide or its equivalent input.

e. Notwithstanding “*a*” through “*d*,” no person shall allow, cause or permit the operation of equipment for the processing of phosphorous ore, rock or other phosphatic material including, but not limited to, phosphoric acid, in a manner that emissions of fluorides exceed 100 pounds per day.

f. “Fluoride” means elemental fluorine and all fluoride compounds as measured by reference methods specified in Appendix A to 40 CFR Part 60 as amended through March 12, 1996.

g. Calculation. The allowable total emission of fluoride shall be calculated by multiplying the unit emission specified above by the expressed design production capacity of the process equipment.

23.4(11) Portland cement concrete batching plants. No person shall cause, allow or permit the operation of a Portland cement concrete batching plant such that the particulate matter discharged to the atmosphere exceeds 0.1 grain per standard cubic foot of exhaust gas.

23.4(12) Incinerators. A person shall not cause, allow or permit the operation of an incinerator unless provided with appropriate control of emissions of particulate matter and visible air contaminants.

a. Particulate matter. A person shall not cause, allow or permit the operation of an incinerator with a rated refuse burning capacity of 1000 or more pounds per hour in a manner such that the particulate matter discharged to the atmosphere exceeds 0.2 grain per standard cubic foot of exhaust gas adjusted to 12 percent carbon dioxide.

A person shall not cause, allow or permit the operation of an incinerator with a rated refuse burning capacity of less than 1000 pounds per hour in a manner such that the particulate matter discharged to the atmosphere exceeds 0.35 grain per standard cubic foot of exhaust gas adjusted to 12 percent carbon dioxide.

b. Visible emissions. A person shall not allow, cause or permit the operation of an incinerator in a manner such that it produces visible air contaminants in excess of 40 percent opacity; except that visible air contaminants in excess of 40 percent opacity but less than or equal to 60 percent opacity may be emitted for periods aggregating not more than 3 minutes in any 60-minute period during an operation breakdown or during the cleaning of air pollution control equipment.

23.4(13) Painting and surface-coating operations. No person shall allow, cause or permit painting and surface-coating operations in a manner such that particulate matter in the gas discharge exceeds 0.01 grain per standard cubic foot of exhaust gas.

This rule is intended to implement Iowa Code section 455B.133.

567—23.5(455B) Anaerobic lagoons.

23.5(1) Applications for construction permits for animal feeding operations using anaerobic lagoons shall meet the requirements of rules 567—65.9(455B) and 567—65.15(455B) to 567—65.17(455B).

23.5(2) Criteria for approval of industrial anaerobic lagoons constructed or expanded on or after July 1, 1982.

a. Lagoons designed to treat 100,000 gallons per day (gpd) or less shall be located at least 1,250 feet from a residence not owned by the owner of the lagoon or from a public use area other than a public road.

b. Lagoons designed to treat more than 100,000 gallons per day (gpd) shall be located at least 1,875 feet from a residence not owned by the owner of the lagoon or from a public use area other than a public road.

c. The criteria in subrule 23.5(2) shall apply except in situations in which Iowa Code section 455B.134(3)“*e*”(2) is successfully invoked.

d. Compliance with the requirements of subrule 23.5(2) shall not constitute an exemption from compliance with any other applicable environmental regulations. In particular, compliance with these requirements shall not absolve any person from compliance with the requirements set forth in 567—Chapter 64 that are applicable to industrial anaerobic lagoons.

This rule is intended to implement Iowa Code section 455B.133.

[ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—23.6(455B) Alternative emission limits (the “bubble concept”). Emission limits for individual emission points included in 567—23.3(455B) (except 23.3(2)“*d*,” 23.3(2)“*b*”(3), and 23.3(3)“*a*”(3))

and 567—23.4(455B) (except 23.4(12) “b” and 23.4(6)) may be replaced by alternative emission limits. The alternative emission limits must be consistent with 567—22.7(455B) and 567—subrule 25.1(12). Under this rule, less stringent control limits where costs of emission control are high may be allowed in exchange for more stringent control limits where costs of control are less expensive.

Rules 567—23.3(455B) to 567—23.6(455B) are intended to implement Iowa Code section 455B.133.

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[◇] Two or more ARCs

¹ Objection, see filed rule [DEQ, 4.2(4)] published IAC Supp. 1/22/77, 3/9/77.

² Effective date of 23.2(4) delayed 70 days by the Administrative Rules Review Committee on 9/14/83.

- ³ 11/24/10 effective date of 23.1(4), introductory paragraph, and 23.1(4)“*ev*” and “*fa*” to “*fd*” delayed 70 days by the Administrative Rules Review Committee at its meeting held November 9, 2010.
- ⁴ Amendment to 23.1(4), introductory paragraph, (ARC 9154B, Item 4) rescinded by Executive Order Number 72 on 4/4/11. Amendment removed and prior language restored IAC Supplement 4/20/11.

CHAPTER 25
MEASUREMENT OF EMISSIONS

[Prior to 7/1/83, DEQ Ch 7]

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—25.1(455B) Testing and sampling of new and existing equipment.

25.1(1) *Continuous monitoring of opacity from coal-fired steam generating units.* The owner or operator of any coal-fired or coal-gas-fired steam generating unit with a rated capacity of greater than 250 million Btus per hour heat input shall install, calibrate, maintain, and operate continuous monitoring equipment to monitor opacity. If an exhaust services more than one steam generating unit as defined in the preceding sentence, the owner has the option of installing opacity monitoring equipment on each unit or on the common stack. Such monitoring equipment shall conform to performance specifications specified in 25.1(9) and shall be operational within 18 months of the date these rules become effective. The director may require the owner or operator of any coal-fired or coal-gas-fired steam generating unit to install, calibrate, maintain and operate continuous monitoring equipment to monitor opacity whenever the compliance status, history of operations, ambient air quality in the vicinity surrounding the generator or the type of control equipment utilized would warrant such monitoring.

25.1(2) and **25.1(3)** Reserved.

25.1(4) *Continuous monitoring of sulfur dioxide from sulfuric acid plants.* The owner or operator of any sulfuric acid plant of greater than 300 tons per day production capacity, the production being expressed as 100 percent acid, shall install, calibrate, maintain and operate continuous monitoring equipment to monitor sulfur dioxide emissions. Said monitoring equipment shall conform to the minimum performance specifications specified in 25.1(9) and shall be operational within 18 months of the date these rules become effective.

25.1(5) *Maintenance of records of continuous monitors.* The owner or operator of any facility which is required to install, calibrate, maintain and operate continuous monitoring equipment shall maintain, for a minimum of two years, a file of all information pertinent to each monitoring system present at the facility. Such information must include but is not limited to all emissions data (raw data, adjusted data, and any or all adjusted factors used to convert emissions from units of measurement to units of the applicable standard), performance evaluations, calibrations and zero checks, and records of all malfunctions of monitoring equipment or source and repair procedures performed.

25.1(6) *Reporting of continuous monitoring information.* The owner or operator of any facility required to install a continuous monitoring system or systems shall provide quarterly reports to the director, no later than 30 calendar days following the end of the calendar quarter, on forms provided by the director. This provision shall not excuse compliance with more stringent applicable reporting requirements. All periods of recorded emissions in excess of the applicable standards, the results of all calibrations and zero checks and performance evaluations occurring during the reporting period, and any periods of monitoring equipment malfunctions or source upsets and any apparent reasons for these malfunctions and upsets shall be included in the report.

25.1(7) *Tests by owner.* The owner of new or existing equipment or the owner's authorized agent shall conduct emission tests to determine compliance with applicable rules in accordance with these requirements.

a. General. The owner of new or existing equipment or the owner's authorized agent shall notify the department in writing not less than 30 days before a required test or before a performance evaluation of a continuous emission monitor to determine compliance with applicable requirements of 567—Chapter 23 or a permit condition. Such notice shall include the time, the place, the name of the person who will conduct the tests and other information as required by the department. If the owner or operator does not provide timely notice to the department, the department shall not consider the test results or performance evaluation results to be a valid demonstration of compliance with applicable rules or permit conditions. Upon written request, the department may allow a notification period of less than 30 days. At the department's request, a pretest meeting shall be held not later than 15 days before the owner or operator conducts the compliance demonstration. A testing protocol shall be

submitted to the department no later than 15 days before the owner or operator conducts the compliance demonstration. A representative of the department shall be permitted to witness the tests. Results of the tests shall be submitted in writing to the director in the form of a comprehensive report within six weeks of the completion of the testing.

b. New equipment. Unless otherwise specified by the department, all new equipment shall be tested by the owner or the owner's authorized agent to determine compliance with applicable emission limits. Tests conducted to demonstrate compliance with the requirements of the rules or a permit shall be conducted within 60 days of achieving maximum production but no later than 180 days of startup, unless a shorter time frame is specified in the permit.

c. Existing equipment. The director may require the owner or the owner's authorized agent to conduct an emission test on any equipment if the director has reason to believe that the equipment does not comply with applicable requirements. Grounds for requiring such a demonstration of compliance include a modification of control or process equipment, age of equipment, or observation of opacities or other parameters outside the range of those indicative of properly maintained and operated equipment. Testing may be required as necessary to determine actual emissions from a source where that source is believed to have a significant impact on the public health or ambient air quality of an area. The director shall provide the owner or agent not less than 30 days to perform the compliance demonstration and shall provide written notice of the requirement.

25.1(8) Tests by department. Representatives of the department may conduct separate and additional air contaminant emission tests and continuous monitor performance tests of an installation on behalf of the state and at the expense of the state. Sampling holes, safe scaffolding and pertinent allied facilities, but not instruments or sensing devices, as needed, shall be requested in writing by the director and shall be provided by and at the expense of the owner of the installation at such points as specified in the request. The owner shall provide a suitable power source to the point or points of testing so that sampling instruments can be operated as required. Analytical results shall be furnished to the owner.

25.1(9) Methods and procedures. Stack sampling and associated analytical methods used to evaluate compliance with emission limitations of 567—Chapter 23 or a permit condition are as follows:

a. Performance test (stack test). A stack test shall be conducted according to EPA reference methods as specified in 40 CFR 51, Appendix M (as amended through November 14, 2018); 40 CFR 60, Appendix A (as amended through November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through November 14, 2018). The owner of the equipment or the owner's authorized agent may use an alternative methodology if the methodology is approved by the department in writing before testing. Each test shall consist of at least three separate test runs. Unless otherwise specified by the department, compliance shall be assessed on the basis of the arithmetic mean of the emissions measured in the three test runs.

b. Continuous monitoring systems. Minimum performance specifications and quality assurance procedures for performance evaluations of continuous monitoring systems are as specified in 40 CFR 60, Appendix B (as amended through November 14, 2018); 40 CFR 60, Appendix F (as amended through November 14, 2018); 40 CFR 75, Appendix A (as amended through August 30, 2016); 40 CFR 75, Appendix B (as amended through August 30, 2016); and 40 CFR 75, Appendix F (as amended through August 30, 2016). The owner of the equipment or the owner's authorized agent may use an alternative methodology for continuous monitoring systems if the methodology is approved by the department in writing before the minimum performance specifications and quality assurance procedures are conducted.

c. Permit and compliance demonstration requirements. After October 24, 2012, all stack sampling and associated analytical methods used to evaluate compliance with emission limitations of 567—Chapter 23 or required in a permit issued by the department pursuant to 567—Chapter 22 or 33 shall be conducted using the methodology referenced in this rule. If stack sampling was required for a compliance demonstration pursuant to 567—Chapter 23 or for a performance test required in a permit issued by the department pursuant to 567—Chapter 22 or 33 before October 24, 2012, and the demonstration or test was not required to be completed before October 24, 2012, then the methodology referenced in this subrule applies retroactively.

25.1(10) Exemptions from continuous monitoring requirements. The owner or operator of any source is exempt if it can be demonstrated that any of the conditions set forth in this subrule are met with the provision that periodic recertification of the existence of these conditions can be requested.

a. An affected source is subject to a new source performance standard promulgated in 40 CFR Part 60 as amended through September 28, 2007.

b. An affected steam generator had an annual capacity factor for calendar year 1974, as reported to the Federal Power Commission, of less than 30 percent or the projected use of the unit indicates the annual capacity factor will not be increased above 30 percent in the future.

c. An affected steam generator is scheduled to be retired from service within five years of the date these rules become effective.

d. Rescinded IAB 1/20/93, effective 2/24/93.

e. The director may provide a temporary exemption from the monitoring and reporting requirements during any period of monitoring system malfunction, provided that the source owner or operator shows, to the satisfaction of the director, that the malfunction was unavoidable and is being repaired as expeditiously as practical.

25.1(11) Extensions. The owner or operator of any source may request an extension of time provided for installation of the required monitor by demonstrating to the director that good faith efforts have been made to obtain and install the monitor in the prescribed time.

25.1(12) Continuous monitoring of sulfur dioxide from emission points involved in an alternative emission control program. The owner or operator of any facility applying for an alternative emission control program under 567—subrule 22.7(1) that involves the trade-off of sulfur dioxide emissions shall install, calibrate, maintain and operate continuous sulfur dioxide monitoring equipment consistent with EPA reference methods (40 CFR Part 60, Appendix B, as amended through September 28, 2007). The equipment shall be operational within three months of EPA approval of an alternative emission control program.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 0330C, IAB 9/19/12, effective 10/24/12; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 4335C, IAB 3/13/19, effective 4/17/19; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—25.2(455B) Continuous emission monitoring under the acid rain program. The continuous emission monitoring requirements for affected units under the acid rain program as provided in 40 CFR Part 75, including Appendices A, B, F and K as amended through August 30, 2016, are adopted by reference.

[ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18]

567—25.3(455B) Mercury emissions testing and monitoring. Any stationary, coal-fired boiler or stationary, coal-fired combustion turbine serving, at any time since the later of November 15, 1990, or the start-up of the unit's combustion chamber, a generator with a nameplate capacity of more than 25 megawatt electrical (MWe) producing electricity for sale is an affected source under the provisions of this rule.

The provisions of this rule expire on April 22, 2015, except for any affected facility that receives an extension to comply with the emission standards for hazardous air pollutants: coal- and oil-fired electric utility steam generating units (EGUs) (40 CFR Part 63, Subpart UUUUU, commonly known as mercury air toxics standards (MATS)). Any facility receiving an extension of the MATS compliance date shall continue to comply with the provisions of this rule until the date the facility is required to comply with MATS or, alternatively, is no longer subject to the MATS compliance requirements. However, facilities complying with the requirements of this rule as specified in subrule 25.3(3), continuous emissions monitoring systems (CEMS), may submit a written request to the department to discontinue concurrent, annual stack tests. The department will evaluate and grant requests on a case-by-case basis, based upon previous stack test results and how recent the last stack test occurred or other extenuating circumstances, such as those that may cause testing conditions to be unrepresentative of normal operations or cause tests to be unsafe to perform. If the department grants a request, the facility will be required to continue operating CEMS and conduct relative accuracy test audits (RATAs), as specified in subrule 25.3(3),

until the facility is required to comply with MATS or, alternatively, is no longer subject to MATS compliance requirements.

25.3(1) Testing frequency and methods. The owner or operator of an affected source shall complete one stack test for mercury in each calendar quarter for four consecutive calendar quarters. Testing shall commence no later than the third calendar quarter in 2010 (July 1 – September 30). At such time as four consecutive quarterly stack tests are completed and the test results are approved in writing by the department, the owner or operator of an affected source shall complete one stack test for mercury in each subsequent calendar year. Stack testing to fulfill the requirements of this subrule shall meet the following conditions:

a. Stack testing shall be conducted according to U.S. EPA Method 29 or according to ASTM Method D6784-02 (Ontario Hydro Method) and shall quantify both vapor phase and particulate bound mercury. Each stack test shall consist of a minimum of three runs at the normal operating load while combusting coal, and the minimum time per run shall be two hours.

b. The owner or operator or the owner's authorized agent shall notify the department in writing not less than 30 days before each stack test. The notice shall include the time, the place, the name of the person who will conduct the test and other information as required by the department. Upon written request, the department may allow a notification period of less than 30 days. At the department's request, a pretest meeting shall be held no later than 15 days before the scheduled test date. A testing protocol shall be submitted to the department no later than 15 days before the scheduled test date. A representative of the department shall be permitted to witness the tests. Within six weeks of the completion of the testing, the results of the tests shall be submitted in writing to the department in the form of a comprehensive test report.

25.3(2) Low mass emitter (LME). In lieu of complying with the requirements of 25.3(1), the owner or operator of an affected source may submit a written request to the department to be classified as a low mass emitter (LME) for mercury. To be eligible for LME classification by the department, the owner or operator shall meet the following conditions:

a. The owner or operator shall complete at least one stack test prior to July 1, 2010, according to U.S. EPA Method 29 or according to ASTM Method D6784-02 (Ontario Hydro Method) and shall quantify both vapor phase and particulate bound mercury. Each stack test shall consist of a minimum of three runs at the normal operating load while combusting coal, and the minimum time per run shall be two hours.

b. The owner or operator or the owner's authorized agent shall notify the department in writing not less than 30 days before each stack test. The notice shall include the time, the place, the name of the person who will conduct the test and other information as required by the department. Upon written request, the department may allow a notification period of less than 30 days. At the department's request, a pretest meeting shall be held no later than 15 days before the scheduled test date. A testing protocol shall be submitted to the department no later than 15 days before the scheduled test date. A representative of the department shall be permitted to witness the tests. Within six weeks of the completion of the testing, the results of the tests shall be submitted in writing to the department in the form of a comprehensive test report.

c. Using the highest mercury concentration measured from any of the stack test runs, the owner or operator shall submit documentation to the department sufficient to demonstrate that the potential annual mercury emissions from the affected source are less than or equal to 29 pounds (464 ounces) per year.

d. Upon written notification of LME classification by the department, the owner or operator of an affected source shall be exempt from the requirements of 25.3(1).

e. If at any time the potential annual mercury emissions from the affected source exceed 29 pounds per year, it shall be the responsibility of the owner or operator of the affected source to notify the department in writing within 30 days.

25.3(3) Continuous emission monitoring systems (CEMS). In lieu of complying with the requirements of 25.3(1), the owner or operator of an affected source may submit a request to the department to record mercury emissions data using a continuous emission monitoring system (CEMS).

To be eligible for department approval to use CEMS, the owner or operator shall meet the following conditions:

a. The owner or operator shall complete at least one stack test concurrently with operating and recording data from the CEMS prior to September 30, 2010, and thereafter on an annual basis, to demonstrate that the CEMS are providing accurate emissions data, as follows:

(1) The stack test conducted concurrently with the CEMS shall be conducted according to U.S. EPA Method 29 or according to ASTM Method D6784-02 (Ontario Hydro Method) and shall quantify both vapor phase and particulate bound mercury. Each stack test shall consist of a minimum of three runs at the normal operating load while combusting coal, and the minimum time per run shall be two hours.

(2) While conducting the concurrent stack test, the owner and operator shall perform a relative accuracy test audit (RATA) and other CEMS certification procedures according to an approved EPA performance protocol. If an approved EPA performance protocol is not available, the owner or operator may submit an alternative CEMS certification protocol in writing to the department for approval. Department approval must be received before the owner or operator conducts the CEMS certification.

b. The owner or operator or the owner's authorized agent shall notify the department in writing not less than 30 days before each stack test conducted concurrently with CEMS. The notice shall include the time, the place, the name of the person who will conduct the test and other information as required by the department. Upon written request, the department may allow a notification period of less than 30 days. At the department's request, a pretest meeting shall be held no later than 15 days before the scheduled test date. Protocols for the stack testing and for the concurrent CEMS operation and data collection shall be submitted to the department no later than 15 days before the scheduled test date. A representative of the department shall be permitted to witness the tests. Results of the tests and CEMS certification shall be submitted in writing to the department in the form of a comprehensive test and CEMS certification report within six weeks of the completion of the testing.

c. The owner or operator of an affected source shall comply with the provisions of 25.3(1) until such time as the department approves use of CEMS.

d. Upon receiving department approval for CEMS use, the owner or operator of an affected source shall operate and record CEMS data, including calibrating each individual CEMS for zero and span on a daily basis, and shall provide all CEMS data to the department upon written request. CEMS certification shall be completed on an annual basis according to the procedures specified in paragraph 25.3(3) "a."

25.3(4) *EPA-required stack testing for mercury.* If the owner or operator of an affected source is required by EPA to complete stack testing for mercury, the owner or operator may submit a written request to the department that the EPA-required stack test be allowed to fulfill all or part of the testing requirements specified in 25.3(1). The department shall consider each such request on a case-by-case basis.

25.3(5) *Affected sources subject to Section 112(g).* The owner or operator of an affected source subject to the requirements of Clean Air Act Section 112(g) shall comply with the requirements contained in permits issued by the department under 567—Chapters 22 and 33.

[ARC 8216B, IAB 10/7/09, effective 11/11/09; ARC 1913C, IAB 3/18/15, effective 4/22/15]

These rules are intended to implement Iowa Code section 455B.133.

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- [Filed ARC 5051C (Notice ARC 4961C, IAB 3/11/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 30
FEES

567—30.1(455B) Purpose. This chapter sets forth requirements to pay fees for specified activities. Rule 567—30.1(455B) adds definitions for this chapter, a duty to correct errors, and an exemption to fee requirements for administrative amendments. Rule 567—30.2(455B) sets forth the requirements for applicants to submit fees for specified activities associated with new source review in 567—Chapter 22, 567—Chapter 31 and 567—Chapter 33. Rule 567—30.3(455B) contains requirements for the submission of demolition and renovation notification fees for the asbestos emission standard for hazardous air pollutants listed in 567—paragraph 23.1(3)“a.” Rule 567—30.4(455B) sets forth the requirements for applicants to submit fees for specified activities associated with the Title V program found in 567—Chapter 22. Rule 567—30.5(455B) sets forth the requirement to convene fee advisory groups. Rule 567—30.6(455B) details the process by which fee levels shall be established, lists the types of fees and the dollar caps on the fee types that the commission may set, and establishes the mechanism for notification of the fee schedule. Rule 567—30.7(455B) details how fee revenues may be expended and specifies the calculated estimate of maximum fee revenues.

The department shall not initiate review and processing of an application submittal from a minor source until all required fees have been paid to the department. Fees are nonrefundable, except as provided in subrule 30.1(4).

30.1(1) Definitions. For purposes of this chapter, the following definitions shall apply:

“*Application submittal*” means one or more applications required under rule 567—22.1(455B) and submitted at the same time or required to be submitted under rule 567—22.4(455B), rule 567—22.5(455B), 567—Chapter 31 or 567—Chapter 33.

“*Electronic format*,” “*electronic submittal*,” and “*electronic submittal format*” mean a software, Internet-based, or other electronic means specified by the department for submitting fees or associated information to the department for the activities specified in this chapter related to, but not limited to, applications, certifications, determination requests, emissions inventories, forms, notifications, payments, permit applications, and registrations. References to these fee or information submittal methods in this chapter may, as specified by the department, include electronic submittal.

“*Major source*” means a “major source” as defined in rule 567—22.100(455B).

“*Minor source*” means any stationary source not included in the definition of “major source” as defined in rule 567—22.100(455B).

“*Regulated air pollutant*” means “regulated air pollutant or contaminant (for fee calculation)” as defined in rule 567—22.100(455B).

30.1(2) Duty to correct errors. If an owner or operator, or the department, finds an error in a fee assessed or collected under this chapter, the owner or operator shall submit to the department revised forms making the necessary corrections to the fee and shall submit the correct fee. Corrected forms shall be submitted as soon as possible after the error is discovered or upon notification by the department. If the error correction results in a determination by the department that a fee was overpaid or that a duplicate fee was submitted, the department will return the overpaid balance of the fee to the applicant.

30.1(3) Exemption to fee requirements for administrative amendments. A fee shall not be required for any of the following:

- a. Corrections of typographical errors;
- b. Corrections of word processing errors;
- c. Changes in the name, address, or telephone number of any person identified in a permit, or similar minor administrative changes at the source;
- d. Changes in ownership or operational control of a source where the department determines that no other change in the permit is necessary, provided that a written agreement that contains a specific date for transfer of permit responsibility, coverage, and liability between the current permittee and the new permittee has been submitted to the department.

30.1(4) Refund of application fee minus administrative cost for permit applications at minor sources. The department may refund the application fee minus administrative costs if the owner or

operator requests to withdraw the application prior to commencement of the technical review of the application.

[ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—30.2(455B) Fees associated with new source review applications. Beginning on January 15, 2016, each owner or operator required to provide an application submittal, including air quality modeling as applicable; registration; permit by rule; and template under 567—subrule 22.1(1), rule 567—22.4(455B), rule 567—22.5(455B), rule 567—22.8(455B), rule 567—22.10(455B), 567—Chapter 31 or 567—Chapter 33, shall pay fees as specified in the fee schedule approved by the commission and posted on the department's website. Fees shall be submitted with forms supplied by the department.

30.2(1) Payment of regulatory applicability determination fee. Beginning on January 15, 2016, each owner or operator requesting a regulatory applicability determination, as specified in 567—paragraph 22.1(3) "a," shall pay fees as specified in the fee schedule approved by the commission and posted on the department's website. Fees shall be submitted with forms provided by the department.

30.2(2) Reserved.

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—30.3(455B) Fees associated with asbestos demolition or renovation notification.

30.3(1) Payment of fees established. Beginning on January 15, 2016, the owner or operator of a site subject to the national emission standard for hazardous air pollutants (NESHAP) for asbestos notifications, adopted by reference in 567—paragraph 23.1(3) "a," shall submit a fee with each required original or each annual notification for each demolition or renovation, including abatement. Fees shall be paid as specified in the fee schedule approved by the commission and posted on the department's website. Fees shall be submitted with the notification forms provided by the department.

30.3(2) Fee not required. A fee shall not be required for the following:

- a. Notifications when the total amount of asbestos to be removed or disturbed is less than 260 linear feet, less than 160 square feet, and less than 35 cubic feet of facility components and is below the reporting thresholds as defined in 40 CFR 61.145 as amended on January 16, 1991;
- b. Notifications of training fires as required in 567—paragraph 23.2(3) "g";
- c. Controlled burning of demolished buildings as required in 567—paragraph 23.2(3) "j";
- d. Revised, canceled, and courtesy notifications. A revision to a previously submitted courtesy notification due to applicability of the notification requirements in 567—paragraph 23.1(3) "a" is considered an original notification and is subject to the fee requirements of subrule 30.3(1).

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—30.4(455B) Fees associated with Title V operating permits.

30.4(1) Payment of Title V application fee. Beginning on January 15, 2016, each owner or operator required to apply for a Title V permit, or a renewal of a Title V permit, shall pay fees as specified in the fee schedule approved by the commission and posted on the department's website. Fees shall be submitted with forms supplied by the department.

30.4(2) Payment of Title V annual emissions fee.

a. *Fee required.* Any person required to obtain a Title V permit shall pay an annual fee based on the first 4,000 tons of each regulated air pollutant, beginning on November 15, 1994. Beginning on July 1, 1996, Title V operating permit fees shall be paid on or before July 1 of each year. The Title V emissions fee shall be based on actual emissions required to be included in the Title V operating permit application and the annual emissions statement for the previous calendar year. The commission shall not set the fee higher than \$70 per ton without adopting the change pursuant to formal rule making.

b. *Fee and documentation due dates.* The fee shall be submitted annually by July 1 with forms specified by the department.

c. *Phase I acid rain sources.* No fee shall be required to be paid for emissions which occurred during the years 1993 through 1999, inclusive, with respect to any Phase I acid rain affected unit under 42 U.S.C. 7651c.

d. Operation in Iowa. The fee for a portable emissions unit or stationary source which operates both in Iowa and out of state shall be calculated only for emissions from the source while it is operating in Iowa.

e. Title V exempted stationary sources. No fee shall be required for emissions until the year in which sources exempted under 567—subrules 22.102(1) and 22.102(2) are required to apply for a Title V permit. Fees shall be paid for the emission year preceding the year in which the application is due and thereafter.

f. Insignificant activities. No fee shall be required for insignificant activities as defined in rule 567—22.103(455B).

[ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 3679C, IAB 3/14/18, effective 4/18/18]

567—30.5(455B) Fee advisory groups. Prior to each March commission meeting, the director shall convene fee advisory groups for the purposes of reviewing a draft budget and providing recommendations to the department regarding establishing or adjusting fees. Any stakeholder may attend meetings of the advisory groups. The meetings will be open to the public. The date of each meeting shall be posted on the department's website 14 days prior to the meeting date.

30.5(1) New source review for major sources fee advisory group. The director shall convene annually a fee advisory group to review the draft budget and major source fees required by rule 567—30.2(455B) and listed in rule 567—30.6(455B). Participants in the advisory group may provide recommendations to the department regarding fees necessary to cover all direct and indirect costs to administer the major source permit program.

30.5(2) New source review for minor sources fee advisory group. The director shall convene annually a fee advisory group which shall not include major sources as defined in subrule 30.1(1). The fee advisory group will review the draft budget and minor source application fees required in rule 567—30.2(455B) and listed in rule 567—30.6(455B). Participants in the fee advisory group shall include, but may not be limited to, any minor sources and their representatives. The advisory group may provide recommendations to the department regarding fees necessary to cover all direct and indirect costs to administer the minor source permit program.

30.5(3) Asbestos fee advisory group. The director shall convene annually an asbestos NESHAP fee advisory group to review the draft budget and asbestos notification fee required by rule 567—30.3(455B) and listed in rule 567—30.6(455B). Participants in the advisory group may provide recommendations to the department regarding fees necessary to cover all direct and indirect costs to administer the asbestos NESHAP program.

30.5(4) Title V fee advisory group. The director shall convene annually a fee advisory group to review the draft budget and Title V emissions and application fees required by rule 567—30.4(455B) and listed in rule 567—30.6(455B). Participants in the advisory group may provide recommendations to the department regarding fees necessary to cover all direct and indirect costs to administer the Title V operating permit program.

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—30.6(455B) Process to establish or adjust fees and notification of fee rates.

30.6(1) Setting the fees. Beginning on January 15, 2016, fees shall be paid as specified in the fee schedule approved by the commission and posted on the department's website. Following the setting of the fee schedule effective January 15, 2016, the department shall submit the proposed budget and fees for major and minor source construction permit programs, the Title V operating permit program, and the asbestos NESHAP program for the following fiscal year to the commission no later than the March commission meeting of each year, at which time the proposal will be available for public comment until such time as the commission acts on the proposal or until the May commission meeting, whichever occurs first. The department's calculated estimate for each fee shall not produce total revenues in excess of limits specified in Iowa Code sections 455B.133B and 455B.133C during any fiscal year. If an established fee amount must be adjusted, the commission shall set the fees no later than the May commission meeting of each year.

Fees established prior to January 15, 2016, shall become effective on January 15, 2016. In subsequent years, adjusted or established fees shall become effective on July 1. A fee not adjusted by the commission shall remain in effect as previously established until the fee is adjusted by the commission.

30.6(2) *Fee types and dollar caps on fee types.* The commission may set fees for the fee types and activities specified in this subrule and shall not set a fee in the fee schedule higher than the levels specified in this subrule without adopting the change pursuant to formal rule making:

a. New source review applications from major sources, which may include:

- (1) Review of each application for a construction permit: \$115 per hour;
- (2) Review of each application for a prevention of significant deterioration permit: \$115 per hour;
- (3) Review of each plantwide applicability limit request, renewal, or reopening: \$115 per hour;
- (4) Review of each regulatory applicability determination: \$115 per hour; and
- (5) Air quality modeling review: \$90 per hour, which may include:

1. Reviewing air quality modeling for construction permit application submittal; prevention of significant deterioration application submittal; and nonattainment new source review project application submittal; and

2. Conducting air quality modeling for construction permit application submittal.

b. New source review applications from minor sources, which may include:

- (1) Each application for a construction permit: \$385;
- (2) Each application for a registration permit: \$100;
- (3) Each application for a permit by rule: \$100; and
- (4) Each application for a permit template: \$100.

c. Asbestos notifications: \$100.

d. Review of each initial or renewal Title V operating permit application: \$100 per hour.

e. Title V annual emissions: \$70 per ton.

30.6(3) *Notification of fee schedule.* Following the initial setting of any fee by the commission, the department shall make available to the public a fee schedule at least 30 days prior to its effective date. If any established fee amount is adjusted, the department shall make available to the public a revised fee schedule at least 30 days prior to its effective date. The fee schedule shall be posted on the department's website.

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

567—30.7(455B) Fee revenue. Each fee program is established to provide revenue for and is limited in use to specific activities.

30.7(1) *New source review application fees from major sources.* In accordance with Iowa Code section 455B.133C(5), new source review fee revenues may be used to fund the direct and indirect costs related to reviewing and acting on applications for new source review permits, including permit revisions submitted by major sources as defined under new source review programs pursuant to the federal Act, and as provided under 567—Chapter 22, 567—Chapter 31, and 567—Chapter 33, as follows:

a. Reviewing and acting on any application for a new source review permit, including the determination of all applicable requirements and dispersion modeling as part of the processing of a permit or permit revision or an applicability determination;

b. General administrative costs of administering new source review programs, including supporting and tracking of any application for a new source review permit and related data entry; and

c. Developing and implementing an expedited new source review permit application process, and additional fees associated with this process.

The calculated estimate of total revenues from new source review application fees from major sources shall not exceed \$1,500,000 during any state fiscal year.

30.7(2) *New source review application fees from minor sources.* In accordance with Iowa Code section 455B.133C(6), minor new source review fee revenues may be used to fund the direct and indirect costs for reviewing and acting on applications submitted by minor air contaminant sources for construction permits and providing for registrations, permits by rule, or template permits in lieu of obtaining construction permits, under minor source new source review programs pursuant to the federal

Clean Air Act Amendments of 1990, including as provided under 567—Chapter 22. The calculated estimate of total revenues from new source review application fees from minor sources shall not exceed \$250,000 during any state fiscal year.

30.7(3) Title V emissions. In accordance with Iowa Code section 455B.133B(5), Title V emissions fee revenues may be used to fund the direct and indirect costs related to:

a. General administrative costs of administering the operating permit program, including the supporting and tracking of operating permit applications, compliance certification, and related data entry.

b. Costs of implementing and enforcing the terms of an operating permit, not including any court costs or other costs associated with an enforcement action, including adequate resources to determine which sources are subject to the program.

c. Costs of emissions and ambient site-specific monitors.

d. Costs of Title V source-specific modeling, analyses or demonstrations.

e. Costs of preparing inventories and tracking emissions.

f. Costs of providing direct support to sources under the small business stationary source technical and environmental compliance assistance program as provided in Iowa Code section 455B.133A.

g. Costs associated with implementing and administering regulatory activities, including programs, as provided for in division II of Iowa Code chapter 455B, other than costs covered by any of the following: operating permit application fees, new source review application fees, or notification fees, pursuant to Iowa Code section 455B.133B(5) “d”(2).

The calculated estimate of total revenues from emissions fees shall not exceed \$8,250,000 during any state fiscal year.

30.7(4) Title V applications. In accordance with Iowa Code section 455B.133B(6), Title V application fee revenues may be used to fund the direct and indirect costs related to reviewing and acting on applications for operating permits submitted by major sources as defined in rule 567—22.100(455B) and sources subject to rule 567—22.101(455B), as follows:

a. Costs of reviewing and acting on any application for an operating permit or operating permit revision.

b. General administrative costs of administering the operating permit program, including the supporting and tracking of operating permit applications and related data entry.

The calculated estimate of total revenues from Title V application fees shall not exceed \$1,250,000 during any state fiscal year.

30.7(5) Asbestos notification. Pursuant to Iowa Code section 455B.133C(7), asbestos notification fee revenues may be used to fund the direct and indirect costs related to implementing and administering the asbestos national emission standard for hazardous air pollutants program pursuant to 567—Chapter 23. The calculated estimate of total revenues from asbestos notification fees shall not exceed \$450,000 during any state fiscal year.

[ARC 2352C, IAB 1/6/16, effective 12/16/15]

These rules are intended to implement Iowa Code sections 455B.133, 455B.133B and 455B.133C.
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CHAPTER 33
SPECIAL REGULATIONS AND CONSTRUCTION PERMIT REQUIREMENTS
FOR MAJOR STATIONARY SOURCES—PREVENTION OF SIGNIFICANT
DETERIORATION (PSD) OF AIR QUALITY

567—33.1(455B) Purpose. This chapter implements the major New Source Review (NSR) program contained in Part C of Title I of the federal Clean Air Act as amended on November 15, 1990, and as promulgated under 40 CFR 51.166 and 52.21 as amended through October 18, 2016. This is a preconstruction review and permitting program applicable to new or modified major stationary sources of air pollutants regulated under Part C of the Clean Air Act as amended on November 15, 1990. In areas that do not meet the national ambient air quality standards (NAAQS), the nonattainment major program applies. The requirements for the nonattainment major NSR program are set forth in 567—22.5(455B), 567—22.6(455B), 567—31.20(455), and 567—31.3(455B). In areas that meet the NAAQS, the PSD program applies. Collectively, the nonattainment major and PSD programs are referred to as the major NSR program. An owner or operator required to apply for a construction permit under 567—Chapter 33 shall submit fees as required in 567—Chapter 30.

Rule 567—33.2(455B) is reserved.

Rule 567—33.3(455B) sets forth the definitions, standards and permitting requirements that are specific to the PSD program.

Rules 567—33.4(455B) through 567—33.8(455B) are reserved.

Rule 567—33.9(455B) includes the conditions under which a source subject to PSD may obtain a plantwide applicability limitation (PAL) on emissions. An owner or operator requesting a PAL under 567—33.9(455B) shall submit fees as required in 567—Chapter 30.

In addition to the requirements in this chapter, stationary sources may also be subject to the permitting requirements in 567—Chapter 22, including requirements for Title V operating permits.

[ARC 9906B, IAB 12/14/11, effective 11/16/11; ARC 1227C, IAB 12/11/13, effective 1/15/14; ARC 2352C, IAB 1/6/16, effective 12/16/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18]

567—33.2(455B) Reserved.

567—33.3(455B) Special construction permit requirements for major stationary sources in areas designated attainment or unclassified (PSD).

33.3(1) Definitions. Definitions included in this subrule apply to the provisions set forth in this rule (PSD program requirements). For purposes of this rule, the definitions herein shall apply, rather than the definitions contained in 40 CFR 52.21 and 51.166, except for the PAL program definitions referenced in rule 567—33.9(455B). For purposes of this rule, the following terms shall have the meanings indicated in this subrule:

“*Act*” means the Clean Air Act, 42 U.S.C. Sections 7401, et seq., as amended through November 15, 1990.

“*Actual emissions*” means:

1. The actual rate of emissions of a regulated NSR pollutant from an emissions unit, as determined in accordance with paragraphs “2” through “4,” except that this definition shall not apply for calculating whether a significant emissions increase has occurred, or for establishing a PAL under rule 567—33.9(455B). Instead, the requirements specified under the definitions for “projected actual emissions” and “baseline actual emissions” shall apply for those purposes.

2. In general, actual emissions as of a particular date shall equal the average rate, in tons per year, at which the unit actually emitted the pollutant during a consecutive 24-month period which precedes the particular date and which is representative of normal source operation. The department shall allow the use of a different time period upon a determination that it is more representative of normal source operation. Actual emissions shall be calculated using the unit’s actual operating hours, production rates, and types of materials processed, stored, or combusted during the selected time period.

3. The department may presume that source-specific allowable emissions for the unit are equivalent to the actual emissions of the unit.

4. For any emissions unit that has not begun normal operations on the particular date, actual emissions shall equal the potential to emit of the unit on that date.

“*Administrator*” means the administrator for the United States Environmental Protection Agency (EPA) or designee.

“*Allowable emissions*” means the emissions rate of a stationary source calculated using the maximum rated capacity of the source (unless the source is subject to federally enforceable limits or enforceable permit conditions which restrict the operating rate, or hours of operation, or both) and the most stringent of the following:

1. The applicable standards as set forth in 567—subrules 23.1(2) through 23.1(5) (new source performance standards, emissions standards for hazardous air pollutants, and federal emissions guidelines) or an applicable federal standard not adopted by the state, as set forth in 40 CFR Parts 60, 61 and 63;

2. The applicable state implementation plan (SIP) emissions limitation, including those with a future compliance date; or

3. The emissions rate specified as an enforceable permit condition, including those with a future compliance date.

“*Baseline actual emissions*,” for the purposes of this chapter, means the rate of emissions, in tons per year, of a regulated NSR pollutant, as “regulated NSR pollutant” is defined in this subrule, and as determined in accordance with paragraphs “1” through “4.”

1. For any existing electric utility steam generating unit, “baseline actual emissions” means the average rate, in tons per year, at which the unit actually emitted the pollutant during any consecutive 24-month period selected by the owner or operator within the five-year period immediately preceding the date on which the owner or operator begins actual construction of the project. The department shall allow the use of a different time period upon a determination that it is more representative of normal source operation.

(a) The average rate shall include fugitive emissions to the extent quantifiable and emissions associated with startups, shutdowns, and malfunctions.

(b) The average rate shall be adjusted downward to exclude any noncompliant emissions that occurred while the source was operating above an emissions limitation that was legally enforceable during the consecutive 24-month period.

(c) For a regulated NSR pollutant, when a project involves multiple emissions units, only one consecutive 24-month period must be used to determine the baseline actual emissions for the emissions units being changed. A different consecutive 24-month period may be used for each regulated NSR pollutant.

(d) The average rate shall not be based on any consecutive 24-month period for which there is inadequate information for determining annual emissions, in tons per year, and for adjusting this amount if required by paragraph “1”(b) of this definition.

2. For an existing emissions unit, other than an electric utility steam generating unit, “baseline actual emissions” means the average rate, in tons per year, at which the emissions unit actually emitted the pollutant during any consecutive 24-month period selected by the owner or operator within the ten-year period immediately preceding either the date on which the owner or operator begins actual construction of the project, or the date on which a complete permit application is received by the department for a permit required either under this chapter or under a SIP approved by the Administrator, whichever is earlier, except that the ten-year period shall not include any period earlier than November 15, 1990.

(a) The average rate shall include fugitive emissions to the extent quantifiable and emissions associated with startups, shutdowns, and malfunctions.

(b) The average rate shall be adjusted downward to exclude any noncompliant emissions that occurred while the source was operating above an emissions limitation that was legally enforceable during the consecutive 24-month period.

(c) The average rate shall be adjusted downward to exclude any emissions that would have exceeded an emissions limitation with which the major stationary source must currently comply, had such major stationary source been required to comply with such limitations during the consecutive

24-month period. However, if an emissions limitation is part of a maximum achievable control technology standard that the Administrator proposed or promulgated under 40 CFR Part 63, the baseline actual emissions need only be adjusted if the state has taken credit for such emissions reductions in an attainment demonstration or maintenance plan consistent with the requirements of 40 CFR 51.165(a)(3)(ii)(G) as amended through November 29, 2005.

(d) For a regulated NSR pollutant, when a project involves multiple emissions units, only one consecutive 24-month period must be used to determine the baseline actual emissions for the emissions units being changed. A different consecutive 24-month period may be used for each regulated NSR pollutant.

(e) The average rate shall not be based on any consecutive 24-month period for which there is inadequate information for determining annual emissions, in tons per year, and for adjusting this amount if required by paragraphs “2”(b) and “2”(c) of this definition.

3. For a new emissions unit, the baseline actual emissions for purposes of determining the emissions increase that will result from the initial construction and operation of such unit shall equal zero; and thereafter, for all other purposes, shall equal the unit’s potential to emit.

4. For a PAL for a stationary source, the baseline actual emissions shall be calculated for existing electric utility steam generating units in accordance with the procedures contained in paragraph “1”; for other existing emissions units in accordance with the procedures contained in paragraph “2”; and for a new emissions unit in accordance with the procedures contained in paragraph “3.”

“Baseline area” means:

1. Any intrastate area (and every part thereof) designated as attainment or unclassifiable under Section 107(d)(1)(A)(ii) or (iii) of the Act in which the major source or major modification establishing the minor source baseline date would construct or would have an air quality impact for the pollutant for which the baseline date is established, as follows: equal to or greater than 1 $\mu\text{g}/\text{m}^3$ (annual average) for sulfur dioxide (SO_2), nitrogen dioxide (NO_2) or PM_{10} ; or equal to or greater than 0.3 $\mu\text{g}/\text{m}^3$ (annual average) for $\text{PM}_{2.5}$.

2. Area redesignations under Section 107(d)(1)(A)(ii) or (iii) of the Act cannot intersect or be smaller than the area of impact of any major stationary source or major modification which establishes a minor source baseline date or is subject to regulations specified in this rule, in 40 CFR 52.21 (PSD requirements), or in department rules approved by EPA under 40 CFR Part 51, Subpart I, and would be constructed in the same state as the state proposing the redesignation.

3. Any baseline area established originally for the total suspended particulate increments shall remain in effect and shall apply for purposes of determining the amount of available PM_{10} increments, except that such baseline area shall not remain in effect if the permitting authority rescinds the corresponding minor source baseline date in accordance with the definition of “baseline date” specified in this subrule.

“Baseline concentration” means:

1. The ambient concentration level that exists in the baseline area at the time of the applicable minor source baseline date. A baseline concentration is determined for each pollutant for which a minor source baseline date is established and shall include:

(a) The actual emissions representative of sources in existence on the applicable minor source baseline date, except as provided in paragraph “2” of this definition;

(b) The allowable emissions of major stationary sources that commenced construction before the major source baseline date, but were not in operation by the applicable minor source baseline date.

2. The following will not be included in the baseline concentration and will affect the applicable maximum allowable increase(s):

(a) Actual emissions from any major stationary source on which construction commenced after the major source baseline date; and

(b) Actual emissions increases and decreases at any stationary source occurring after the minor source baseline date.

“Baseline date” means:

1. Either “major source baseline date” or “minor source baseline date” as follows:

(a) The “major source baseline date” means, in the case of PM₁₀ and sulfur dioxide, January 6, 1975; in the case of nitrogen dioxide, February 8, 1988; and in the case of PM_{2.5}, October 20, 2010.

(b) The “minor source baseline date” means the earliest date after the trigger date on which a major stationary source or a major modification subject to 40 CFR 52.21 as amended through October 20, 2010, or subject to this rule (PSD program requirements), or subject to a department rule approved by EPA under 40 CFR Part 51, Subpart I, submits a complete application under the relevant regulations. The trigger date for PM₁₀ and sulfur dioxide is August 7, 1977. For nitrogen dioxide, the trigger date is February 8, 1988. For PM_{2.5}, the trigger date is October 20, 2011.

2. The “baseline date” is established for each pollutant for which increments or other equivalent measures have been established if:

(a) The area in which the proposed source or modification would construct is designated as attainment or unclassifiable under Section 107(d)(1)(A)(ii) or (iii) of the Act for the pollutant on the date of its complete application under 40 CFR 52.21 as amended through October 20, 2010, or under regulations specified in this rule (PSD program requirements); and

(b) In the case of a major stationary source, the pollutant would be emitted in significant amounts, or in the case of a major modification, there would be a significant net emissions increase of the pollutant.

Any minor source baseline date established originally for the total suspended particulate increments shall remain in effect and shall apply for purposes of determining the amount of available PM₁₀ increments, except that the reviewing authority may rescind any such minor source baseline date where it can be shown, to the satisfaction of the reviewing authority, that the emissions increase from the major stationary source, or the net emissions increase from the major modification, responsible for triggering that date did not result in a significant amount of PM₁₀ emissions.

“*Begin actual construction*” means, in general, initiation of physical on-site construction activities on an emissions unit which are of a permanent nature. Such activities include, but are not limited to, installation of building supports and foundations, laying of underground pipework, and construction of permanent storage structures. With respect to a change in method of operation, this term refers to those on-site activities, other than preparatory activities, which mark the initiation of the change.

“*Best available control technology*” or “*BACT*” means an emissions limitation, including a visible emissions standard, based on the maximum degree of reduction for each regulated NSR pollutant which would be emitted from any proposed major stationary source or major modification which the reviewing authority, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such source or modification through application of production processes or available methods, systems, and techniques, including fuel cleaning or treatment or innovative fuel combination techniques for control of such pollutant. In no event shall application of best available control technology result in emissions of any pollutant which would exceed the emissions allowed by any applicable standard under 567—subrules 23.1(2) through 23.1(5) (standards for new stationary sources, federal standards for hazardous air pollutants, and federal emissions guidelines), or federal regulations as set forth in 40 CFR Parts 60, 61 and 63 but not yet adopted by the state. If the department determines that technological or economic limitations on the application of measurement methodology to a particular emissions unit would make the imposition of an emissions standard infeasible, a design, equipment, work practice, operational standard or combination thereof may be prescribed instead to satisfy the requirement for the application of best available control technology. Such standard shall, to the degree possible, set forth the emissions reduction achievable by implementation of such design, equipment, work practice or operation and shall provide for compliance by means which achieve equivalent results.

“*Building, structure, facility, or installation*” means all of the pollutant-emitting activities which belong to the same industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same person (or persons under common control) except the activities of any vessel. Pollutant-emitting activities shall be considered as part of the same industrial grouping if they belong to the same major group (i.e., which have the same two-digit code) as described in the Standard Industrial Classification Manual, 1972, as amended by the 1977 Supplement (U.S. Government Printing Office stock numbers 4101-0066 and 003-005-00176-0, respectively).

“CFR” means the Code of Federal Regulations, with standard references in this chapter by title and part, so that “40 CFR 51” or “40 CFR Part 51” means “Title 40 Code of Federal Regulations, Part 51.”

“Clean coal technology” means any technology, including technologies applied at the precombustion, combustion, or postcombustion stage, at a new or existing facility which will achieve significant reductions in air emissions of sulfur dioxide or oxides of nitrogen associated with the utilization of coal in the generation of electricity, or process steam which was not in widespread use as of November 15, 1990.

“Clean coal technology demonstration project” means a project using funds appropriated under the heading “Department of Energy—Clean Coal Technology,” up to a total amount of \$2,500,000,000 for commercial demonstration of clean coal technology, or similar projects funded through appropriations for the Environmental Protection Agency. The federal contribution for a qualifying project shall be at least 20 percent of the total cost of the demonstration project.

“Commence,” as applied to construction of a major stationary source or major modification, means that the owner or operator has all necessary preconstruction approvals or permits and either has:

1. Begun, or caused to begin, a continuous program of actual on-site construction of the source, to be completed within a reasonable time; or

2. Entered into binding agreements or contractual obligations, which cannot be canceled or modified without substantial loss to the owner or operator, to undertake a program of actual construction of the source to be completed within a reasonable time.

“Complete” means, in reference to an application for a permit, that the application contains all the information necessary for processing the application. Designating an application complete for purposes of permit processing does not preclude the department from requesting or accepting any additional information.

“Construction” means any physical change or change in the method of operation, including fabrication, erection, installation, demolition, or modification of an emissions unit, that would result in a change in emissions.

“Continuous emissions monitoring system” or “CEMS” means all of the equipment that may be required to meet the data acquisition and availability requirements of this chapter, to sample, to condition (if applicable), to analyze, and to provide a record of emissions on a continuous basis.

“Continuous emissions rate monitoring system” or “CERMS” means the total equipment required for the determination and recording of the pollutant mass emissions rate (in terms of mass per unit of time).

“Continuous parameter monitoring system” or “CPMS” means all of the equipment necessary to meet the data acquisition and availability requirements of this chapter, to monitor the process device operational parameters and the control device operational parameters (e.g., control device secondary voltages and electric currents) and other information (e.g., gas flow rate, O₂ or CO₂ concentrations), and to record the average operational parameter value(s) on a continuous basis.

“Electric utility steam generating unit” means any steam electric generating unit that is constructed for the purpose of supplying more than one-third of its potential electric output capacity and more than 25 MW electrical output to any utility power distribution system for sale. Any steam supplied to a steam distribution system for the purpose of providing steam to a steam-electric generator that would produce electrical energy for sale is also considered in determining the electrical energy output capacity of the affected facility.

“Emissions unit” means any part of a stationary source that emits or would have the potential to emit any regulated NSR pollutant and includes an electric utility steam generating unit. For purposes of this chapter, there are two types of emissions units:

1. A new emissions unit is any emissions unit that is (or will be) newly constructed and that has existed for less than two years from the date such emissions unit first operated.

2. An existing emissions unit is any emissions unit that does not meet the requirements in “1” above. A replacement unit is an existing emissions unit.

“Enforceable permit condition,” for the purpose of this chapter, means any of the following limitations and conditions: requirements developed pursuant to new source performance standards,

prevention of significant deterioration standards, emissions standards for hazardous air pollutants, requirements within the SIP, and any permit requirements established pursuant to this chapter, any permit requirements established pursuant to 40 CFR 52.21 or Part 51, Subpart I, as amended through October 20, 2010, or under construction or Title V operating permit rules.

"Federal land manager" means, with respect to any lands in the United States, the secretary of the department with authority over such lands.

"Federally enforceable" means all limitations and conditions which are enforceable by the Administrator and the department, including those federal requirements not yet adopted by the state, developed pursuant to 40 CFR Parts 60, 61 and 63; requirements within 567—subrules 23.1(2) through 23.1(5); requirements within the SIP; any permit requirements established pursuant to 40 CFR 52.21 or under regulations approved pursuant to 40 CFR Part 51, Subpart I, as amended through October 20, 2010, including operating permits issued under an EPA-approved program, that are incorporated into the SIP and expressly require adherence to any permit issued under such program.

"Fugitive emissions" means those emissions which could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening.

"High terrain" means any area having an elevation 900 feet or more above the base of the stack of a source.

"Indian governing body" means the governing body of any tribe, band, or group of Indians subject to the jurisdiction of the United States and recognized by the United States as possessing power of self-government.

"Indian reservation" means any federally recognized reservation established by treaty, agreement, executive order, or Act of Congress.

"Innovative control technology" means any system of air pollution control that has not been adequately demonstrated in practice, but would have a substantial likelihood of achieving greater continuous emissions reduction than any control system in current practice or of achieving at least comparable reductions at lower cost in terms of energy, economics, or non-air quality environmental impacts.

"Lowest achievable emissions rate" or *"LAER"* means, for any source, the more stringent rate of emissions based on the following:

1. The most stringent emissions limitation which is contained in the SIP for such class or category of stationary source, unless the owner or operator of the proposed stationary source demonstrates that such limitations are not achievable; or

2. The most stringent emissions limitation which is achieved in practice by such class or category of stationary sources. This limitation, when applied to a modification, means the lowest achievable emissions rate for the new or modified emissions units within a stationary source. In no event shall the application of the term permit a proposed new or modified stationary source to emit any pollutant in excess of the amount allowable under an applicable new source standard of performance.

"Low terrain" means any area other than high terrain.

"Major modification" means any physical change in or change in the method of operation of a major stationary source that would result in a significant emissions increase of a regulated NSR pollutant and a significant net emissions increase of that pollutant from the major stationary source.

1. Any significant emissions increase from any emissions units or net emissions increase at a major stationary source that is significant for volatile organic compounds or NO_x shall be considered significant for ozone.

2. A physical change or change in the method of operation shall not include:

- (a) Routine maintenance, repair and replacement
- (b) Use of an alternative fuel or raw material by reason of any order under Section 2(a) and (b) of the Energy Supply and Environmental Coordination Act of 1974 or by reason of a natural gas curtailment plan pursuant to the Federal Power Act;
- (c) Use of an alternative fuel by reason of an order or rule under Section 125 of the Act;
- (d) Use of an alternative fuel at a steam generating unit to the extent that the fuel is generated from municipal solid waste;

(e) Use of an alternative fuel or raw material by a stationary source that the source was capable of accommodating before January 6, 1975, unless such change would be prohibited under any federally enforceable permit condition, or that the source is approved to use under any federally enforceable permit condition;

(f) An increase in the hours of operation or in the production rate, unless such change would be prohibited under any federally enforceable permit condition which was established after January 6, 1975;

(g) Any change in ownership at a stationary source;

(h) Reserved.

(i) The installation, operation, cessation, or removal of a temporary clean coal technology demonstration project, provided that the project complies with the requirements within the SIP; and other requirements necessary to attain and maintain the national ambient air quality standards during the project and after the project is terminated;

(j) The installation or operation of a permanent clean coal technology demonstration project that constitutes repowering, provided that the project does not result in an increase in the potential to emit of any regulated pollutant emitted by the unit. This exemption shall apply on a pollutant-by-pollutant basis;

(k) The reactivation of a very clean coal-fired electric utility steam generating unit.

3. This definition shall not apply with respect to a particular regulated NSR pollutant when the major stationary source is complying with the requirements under rule 567—33.9(455B) for a PAL for that pollutant. Instead, the definition under rule 567—33.9(455B) shall apply.

“Major source baseline date” is defined under the definition of “baseline date.”

“Major stationary source” means:

(1) (a) Any one of the following stationary sources of air pollutants which emits, or has the potential to emit, 100 tons per year or more of any regulated NSR pollutant:

- Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;

- Coal cleaning plants (with thermal dryers);

- Kraft pulp mills;

- Portland cement plants;

- Primary zinc smelters;

- Iron and steel mill plants;

- Primary aluminum ore reduction plants;

- Primary copper smelters;

- Municipal incinerators capable of charging more than 250 tons of refuse per day;

- Hydrofluoric, sulfuric, and nitric acid plants;

- Petroleum refineries;

- Lime plants;

- Phosphate rock processing plants;

- Coke oven batteries;

- Sulfur recovery plants;

- Carbon black plants (furnace process);

- Primary lead smelters;

- Fuel conversion plants;

- Sintering plants;

- Secondary metal production plants;

- Chemical process plants (which does not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS code 325193 or 312140);

- Fossil-fuel boilers (or combinations thereof) totaling more than 250 million British thermal units per hour heat input;

- Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;

- Taconite ore processing plants;

- Glass fiber processing plants; and

- Charcoal production plants.

(b) Notwithstanding the stationary source size specified in paragraph “1”(a), any stationary source which emits, or has the potential to emit, 250 tons per year or more of a regulated NSR pollutant; or

(c) Any physical change that would occur at a stationary source not otherwise qualifying under this definition as a major stationary source if the change would constitute a major stationary source by itself.

(2) A major source that is major for volatile organic compounds or NO_x shall be considered major for ozone.

(3) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this rule whether it is a major stationary source, unless the source belongs to one of the categories of stationary sources listed in paragraph “1”(a) of this definition or to any other stationary source category which, as of August 7, 1980, is being regulated under Section 111 or 112 of the Act.

“*Minor source baseline date*” is defined under the definition of “baseline date.”

“*Necessary preconstruction approvals or permits*” means those permits or approvals required under federal air quality control laws and regulations and those air quality control laws and regulations which are part of the SIP.

“*Net emissions increase*” means, with respect to any regulated NSR pollutant emitted by a major stationary source, the amount by which the following exceeds zero:

- The increase in emissions from a particular physical change or change in the method of operation at a stationary source as calculated according to the applicability requirements under subrule 33.3(2); and

- Any other increases and decreases in actual emissions at the major stationary source that are contemporaneous with the particular change and are otherwise creditable. Baseline actual emissions for calculating increases and decreases under this definition of “net emissions increase” shall be determined as provided for under the definition of “baseline actual emissions,” except that paragraphs “1”(c) and “2”(d) of the definition of “baseline actual emissions,” which describe provisions for multiple emissions units, shall not apply.

1. An increase or decrease in actual emissions is contemporaneous with the increase from the particular change only if the increase or decrease in actual emissions occurs between the date five years before construction on the particular change commences and the date that the increase from the particular change occurs.

2. An increase or decrease in actual emissions is creditable only if:

- (a) The increase or decrease in actual emissions occurs within the contemporaneous time period, as noted in paragraph “1” of this definition; and

- (b) The department has not relied on the increase or decrease in actual emissions in issuing a permit for the source under this rule, which permit is in effect when the increase in actual emissions from the particular change occurs.

3. An increase or decrease in actual emissions of sulfur dioxide, particulate matter, or nitrogen oxides that occurs before the applicable minor source baseline date is creditable only if the increase or decrease in actual emissions is required to be considered in calculating the amount of maximum allowable increases remaining available.

4. An increase in actual emissions is creditable only to the extent that the new level of actual emissions exceeds the old level.

5. A decrease in actual emissions is creditable only to the extent that:

- (a) The old level of actual emissions or the old level of allowable emissions, whichever is lower, exceeds the new level of actual emissions;

- (b) The decrease in actual emissions is enforceable as a practical matter at and after the time that actual construction on the particular change begins; and

- (c) The decrease in actual emissions has approximately the same qualitative significance for public health and welfare as that attributed to the increase from the particular change.

6. An increase that results from a physical change at a source occurs when the emissions unit on which construction occurred becomes operational and begins to emit a particular pollutant. Any replacement unit that requires shakedown becomes operational only after a reasonable shakedown period, not to exceed 180 days.

7. The definition of “actual emissions,” paragraph “2,” shall not apply for determining creditable increases and decreases.

“*Nonattainment area*” means an area so designated by the Administrator, acting pursuant to Section 107 of the Act.

“*Permitting authority*” means the Iowa department of natural resources or the director thereof.

“*Pollution prevention*” means any activity that, through process changes, product reformulation or redesign, or substitution of less polluting raw materials, eliminates or reduces the release of air pollutants (including fugitive emissions) and other pollutants to the environment prior to recycling, treatment, or disposal. “Pollution prevention” does not mean recycling (other than certain “in-process recycling” practices), energy recovery, treatment, or disposal.

“*Potential to emit*” means the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable. Secondary emissions do not count in determining the potential to emit of a stationary source.

“*Predictive emissions monitoring system*” or “*PEMS*” means all of the equipment necessary to monitor the process device operational parameters and the control device operational parameters (e.g., control device secondary voltages and electric currents) and other information (e.g., gas flow rate, O₂ or CO₂ concentrations), and calculate and record the mass emissions rate (e.g., lb/hr) on a continuous basis.

“*Prevention of significant deterioration (PSD) program*” means a major source preconstruction permit program that has been approved by the Administrator and incorporated into the SIP or means the program in 40 CFR 52.21. Any permit issued under such a program is a major NSR permit.

“*Project*” means a physical change in, or change in method of operation of, an existing major stationary source.

“*Projected actual emissions,*” for the purposes of this chapter, means the maximum annual rate, in tons per year, at which an existing emissions unit is projected to emit a regulated NSR pollutant in any one of the five years (12-month period) beginning on the first day of the month following the date when the unit resumes regular operation after the project, or in any one of the ten years following that date, if the project involves increasing the emissions unit’s design capacity or its potential to emit that regulated NSR pollutant, and full utilization of the unit would result in a significant emissions increase, or a significant net emissions increase at the major stationary source. For purposes of this definition, “regular” shall be determined by the department on a case-by-case basis.

In determining the projected actual emissions before beginning actual construction, the owner or operator of the major stationary source:

1. Shall consider all relevant information including, but not limited to, historical operational data, the company’s own representations, the company’s expected business activity and the company’s highest projections of business activity, the company’s filings with the state or federal regulatory authorities, and compliance plans under the approved plan; and

2. Shall include fugitive emissions to the extent quantifiable and emissions associated with startups, shutdowns, and malfunctions; and

3. Shall exclude, in calculating any increase in emissions that results from the particular project, that portion of the unit’s emissions following the project that an existing unit could have accommodated during the consecutive 24-month period used to establish the baseline actual emissions and that are also unrelated to the particular project, including any increased utilization due to product demand growth; and

4. In lieu of using the method set out in paragraphs “1” through “3,” may elect to use the emissions unit’s potential to emit, in tons per year.

“*Reactivation of a very clean coal-fired electric utility steam generating unit*” means any physical change or change in the method of operation associated with the commencement of commercial operations by a coal-fired utility unit after a period of discontinued operation in which the unit:

1. Has not been in operation for the two-year period prior to the enactment of the Act, and the emissions from such unit continue to be carried in the permitting authority's emissions inventory at the time of the enactment;

2. Was equipped prior to shutdown with a continuous system of emissions control that achieves a removal efficiency for sulfur dioxide of no less than 85 percent and a removal efficiency for particulates of no less than 98 percent;

3. Is equipped with low-NO_x burners prior to the time of commencement of operations following reactivation; and

4. Is otherwise in compliance with the requirements of the Act.

"Regulated NSR pollutant" means the following:

1. Any pollutant for which a national ambient air quality standard has been promulgated and any constituents or precursors for such pollutants identified by the Administrator:

(a) Volatile organic compounds and nitrogen oxides are precursors to ozone in all attainment and unclassifiable areas;

(b) Sulfur dioxide is a precursor to PM_{2.5} in all attainment and unclassifiable areas;

(c) Nitrogen oxides are presumed to be precursors to PM_{2.5} in all attainment and unclassifiable areas, unless the department demonstrates to EPA's satisfaction or EPA demonstrates that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to the area's ambient PM_{2.5} concentrations;

(d) Volatile organic compounds are presumed not to be precursors to PM_{2.5} in any attainment and unclassifiable areas, unless the department demonstrates to EPA's satisfaction or EPA demonstrates that emissions of volatile organic compounds from sources in a specific area are a significant contributor to that area's ambient PM_{2.5} concentrations;

2. Any pollutant that is subject to any standard promulgated under Section 111 of the Act;

3. Any Class I or Class II substance subject to a standard promulgated under or established by Title VI of the Act; or

4. Any pollutant that otherwise is subject to regulation under the Act as defined in 33.3(1), definition of "subject to regulation."

5. Notwithstanding paragraphs "1" through "4," the definition of "regulated NSR pollutant" shall not include any or all hazardous air pollutants that are either listed in Section 112 of the Act or added to the list pursuant to Section 112(b)(2) of the Act and that have not been delisted pursuant to Section 112(b)(3) of the Act, unless the listed hazardous air pollutant is also regulated as a constituent or precursor of a general pollutant listed under Section 108 of the Act.

6. Particulate matter (PM) emissions, PM_{2.5} emissions and PM₁₀ emissions shall include gaseous emissions from a source or activity which condense to form particulate matter at ambient temperatures.

"Replacement unit" means an emissions unit for which all the criteria listed in paragraphs "1" through "4" of this definition are met. No creditable emissions reductions shall be generated from shutting down the existing emissions unit that is replaced.

1. The emissions unit is a reconstructed unit within the meaning of 40 CFR 60.15(b)(1) as amended through December 16, 1975, or the emissions unit completely takes the place of an existing emissions unit.

2. The emissions unit is identical to or functionally equivalent to the replaced emissions unit.

3. The replacement does not change the basic design parameter(s) of the process unit.

4. The replaced emissions unit is permanently removed from the major stationary source, otherwise permanently disabled, or permanently barred from operation by a permit that is enforceable as a practical matter. If the replaced emissions unit is brought back into operation, it shall constitute a new emissions unit.

"Repowering" means:

1. Replacement of an existing coal-fired boiler with one of the following clean coal technologies: atmospheric or pressurized fluidized bed combustion; integrated gasification combined cycle; magnetohydrodynamics; direct and indirect coal-fired turbines; integrated gasification fuel cells; or, as determined by the Administrator in consultation with the Secretary of Energy, a derivative of one

or more of these technologies; and any other technology capable of controlling multiple combustion emissions simultaneously with improved boiler or generation efficiency and with significantly greater waste reduction relative to the performance of technology in widespread commercial use as of November 15, 1990.

2. Repowering shall also include any oil or gas-fired unit which has been awarded clean coal technology demonstration funding as of January 1, 1991, by the Department of Energy.

3. The department shall give expedited consideration to permit applications for any source that satisfies the requirements of this definition and is granted an extension under Section 409 of the Act.

“*Reviewing authority*” means the department, or the Administrator in the case of EPA-implemented permit programs under 40 CFR 52.21.

“*Secondary emissions*” means emissions which occur as a result of the construction or operation of a major stationary source or major modification, but do not come from the major stationary source or major modification itself. For the purposes of this chapter, “secondary emissions” must be specific, well-defined, and quantifiable, and must impact the same general areas as the stationary source modification which causes the secondary emissions. “Secondary emissions” includes emissions from any offsite support facility which would not be constructed or increase its emissions except as a result of the construction or operation of the major stationary source or major modification. “Secondary emissions” does not include any emissions which come directly from a mobile source, such as emissions from the tailpipe of a motor vehicle, from a train, or from a vessel.

“*Significant*” means:

1. In reference to a net emissions increase or the potential of a source to emit any of the following pollutants, a rate of emissions that would equal or exceed any of the following rates:

Pollutant and Emissions Rate

- Carbon monoxide: 100 tons per year (tpy)
- Nitrogen oxides: 40 tpy
- Sulfur dioxide: 40 tpy
- Particulate matter: 25 tpy of particulate matter emissions
- PM₁₀: 15 tpy
- PM_{2.5}: 10 tpy of direct PM_{2.5} emissions; 40 tpy of sulfur dioxide emissions; 40 tpy of nitrogen oxide emissions (unless the department demonstrates to EPA’s satisfaction that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to the area’s ambient PM_{2.5} concentrations)
- Ozone: 40 tpy of volatile organic compounds or NO_x
- Lead: 0.6 tpy
- Fluorides: 3 tpy
- Sulfuric acid mist: 7 tpy
- Hydrogen sulfide (H₂S): 10 tpy
- Total reduced sulfur (including H₂S): 10 tpy
- Reduced sulfur compounds (including H₂S): 10 tpy
- Municipal waste combustor organics (measured as total tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans): 3.2×10^{-6} megagrams per year (3.5×10^{-6} tons per year)
- Municipal waste combustor metals (measured as particulate matter): 14 megagrams per year (15 tons per year)
- Municipal waste combustor acid gases (measured as sulfur dioxide and hydrogen chloride): 36 megagrams per year (40 tons per year)
- Municipal solid waste landfill emissions (measured as nonmethane organic compounds): 45 megagrams per year (50 tons per year)

2. “Significant” means, for purposes of this rule and in reference to a net emissions increase or the potential of a source to emit a regulated NSR pollutant not listed in paragraph “1,” any emissions rate.

3. Notwithstanding paragraph “1,” “significant,” for purposes of this rule, means any emissions rate or any net emissions increase associated with a major stationary source or major modification, which

would construct within ten kilometers of a Class I area and have an impact on such area equal to or greater than 1 $\mu\text{g}/\text{m}^3$ (24-hour average).

“*Significant emissions increase*” means, for a regulated NSR pollutant, an increase in emissions that is significant for that pollutant.

“*State implementation plan*” or “*SIP*” means the plan adopted by the state of Iowa and approved by the Administrator which provides for implementation, maintenance, and enforcement of such primary and secondary ambient air quality standards as they are adopted by the Administrator, pursuant to the Act.

“*Stationary source*” means any building, structure, facility, or installation which emits or may emit a regulated NSR pollutant.

“*Subject to regulation*” means, for any air pollutant, that the pollutant is subject to either a provision in the Clean Air Act, or a nationally applicable regulation codified by the Administrator in 40 CFR Subchapter C (Air Programs) that requires actual control of the quantity of emissions of that pollutant, and that such a control requirement has taken effect and is operative to control, limit or restrict the quantity of emissions of that pollutant released from the regulated activity, except that:

1. Greenhouse gases (GHGs), the air pollutant defined in 40 CFR §86.1818-12(a) (as amended through September 15, 2011) as the aggregate group of six greenhouse gases that includes carbon dioxide, nitrous oxide, methane, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride, shall not be subject to regulation except as provided in paragraph “4,” and shall not be subject to regulation if the stationary source maintains its total sourcewide emissions below the GHG PAL level, meets the requirements in rule 567—33.9(455B), and complies with the PAL permit containing the GHG PAL.

2. For purposes of paragraphs “3” and “4,” the term “tpy CO₂ equivalent emissions (CO₂e)” shall represent an amount of GHGs emitted and shall be computed as follows:

(a) Multiply the mass amount of emissions (tpy) for each of the six greenhouse gases in the pollutant GHGs by the associated global warming potential of the gas published at 40 CFR Part 98, Subpart A, Table A-1, “Global Warming Potentials,” (as amended through December 24, 2014). For purposes of this definition, prior to July 21, 2014, the mass of the greenhouse gas carbon dioxide shall not include carbon dioxide emissions resulting from the combustion or decomposition of non-fossilized and biodegradable organic material originating from plants, animals, or micro-organisms (including products, by-products, residues and waste from agriculture, forestry and related industries as well as the non-fossilized and biodegradable organic fractions of industrial and municipal wastes, including gases and liquids recovered from the decomposition of non-fossilized and biodegradable organic material).

(b) Sum the resultant value from paragraph (a) for each gas to compute a tpy CO₂e.

3. The term “emissions increase,” as used in this paragraph and in paragraph “4,” shall mean that both a significant emissions increase (as calculated using the procedures specified in 33.3(2) “c” through 33.3(2) “h”) and a significant net emissions increase (as specified in 33.3(1), in the definitions of “net emissions increase” and “significant”) occur. For the pollutant GHGs, an emissions increase shall be based on tpy CO₂e and shall be calculated assuming the pollutant GHGs are a regulated NSR pollutant, and “significant” is defined as 75,000 tpy CO₂e rather than calculated by applying the value specified in 33.3(1), in paragraph “2” of the definition of “significant.”

4. Beginning January 2, 2011, the pollutant GHGs are subject to regulation if:

(a) The stationary source is a new major stationary source for a regulated NSR pollutant that is not a GHG, and also will emit or will have the potential to emit 75,000 tpy CO₂e or more, or

(b) The stationary source is an existing major stationary source for a regulated NSR pollutant that is not a GHG, and also will have an emissions increase of a regulated NSR pollutant and an emissions increase of 75,000 tpy CO₂e or more.

“*Temporary clean coal technology demonstration project*” means a clean coal technology demonstration project that is operated for a period of five years or less and that complies with the SIP and other requirements necessary to attain and maintain the national ambient air quality standards during the project and after the project is terminated.

“*Title V permit*” means an operating permit under Title V of the Act.

“*Volatile organic compounds*” or “*VOC*” means any compound included in the definition of “volatile organic compounds” found at 40 CFR Section 51.100(s) as amended through November 28, 2018.

33.3(2) *Applicability.* The requirements of this rule (PSD program requirements) apply to the construction of any new “major stationary source” as defined in subrule 33.3(1) or any project at an existing major stationary source in an area designated as attainment or unclassifiable under Section 107(d)(1)(A)(ii) or (iii) of the Act. In addition to the provisions set forth in rules 567—33.3(455B) through 567—33.9(455B), the provisions of 40 CFR Part 51, Appendix W (Guideline on Air Quality Models) as amended through January 17, 2017, are adopted by reference.

a. The requirements of subrules 33.3(10) through 33.3(18) apply to the construction of any new major stationary source or the major modification of any existing major stationary source, except as this rule (PSD program requirements) otherwise provides.

b. No new major stationary source or major modification to which the requirements of subrule 33.3(10) through paragraph 33.3(18) “*e*” apply shall begin actual construction without a permit that states that the major stationary source or major modification will meet those requirements.

c. Except as otherwise provided in paragraphs 33.3(2) “*i*” and “*j*,” and consistent with the definition of “major modification” contained in subrule 33.3(1), a project is a major modification for a “regulated NSR pollutant” if it causes two types of emissions increases: a “significant emissions increase”; and a “net emissions increase” which is “significant.” The project is not a major modification if it does not cause a significant emissions increase. If the project causes a significant emissions increase, then the project is a major modification only if it also results in a significant net emissions increase.

d. The procedure for calculating (before beginning actual construction) whether a significant emissions increase (i.e., the first step of the process) will occur depends upon the type of emissions units being modified, according to paragraphs “*e*” through “*h*” of this subrule. The procedure for calculating (before beginning actual construction) whether a significant net emissions increase will occur at the major stationary source (i.e., the second step of the process) is contained in the definition of “net emissions increase.” Regardless of any such preconstruction projections, a major modification results if the project causes a significant emissions increase and a significant net emissions increase.

e. Actual-to-projected-actual applicability test for projects that only involve existing emissions units. A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the “projected actual emissions” and the “baseline actual emissions” for each existing emissions unit equals or exceeds the significant amount for that pollutant.

f. Actual-to-potential test for projects that involve only construction of a new emissions unit(s). A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the “potential to emit” from each new emissions unit following completion of the project and the “baseline actual emissions” for a new emissions unit before the project equals or exceeds the significant amount for that pollutant.

g. Reserved.

h. Hybrid test for projects that involve multiple types of emissions units. A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the emissions increases for each emissions unit, using the method specified in paragraphs “*e*” through “*g*” of this subrule, as applicable with respect to each emissions unit, for each type of emissions unit equals or exceeds the significant amount for that pollutant.

i. For any major stationary source with a PAL for a regulated NSR pollutant, the major stationary source shall comply with rule requirements under 567—33.9(455B).

j. Reserved.

33.3(3) *Ambient air increments.* The provisions for ambient air increments as specified in 40 CFR 52.21(c) as amended through October 20, 2010, are adopted by reference.

33.3(4) *Ambient air ceilings.* The provisions for ambient air ceilings as specified in 40 CFR 52.21(d) as amended through November 29, 2005, are adopted by reference.

33.3(5) *Restrictions on area classifications.* The provisions for restrictions on area classifications as specified in 40 CFR 52.21(e) as amended through November 29, 2005, are adopted by reference.

33.3(6) Exclusions from increment consumption. The provisions by which the SIP may provide for exclusions from increment consumption as specified in 40 CFR 51.166(f) as amended through November 29, 2005, are adopted by reference. The following phrases contained in 40 CFR 51.166(f) are not adopted by reference: “the plan may provide that,” “the plan provides that,” and “it shall also provide that.” Additionally, the term “the plan” shall mean “SIP.”

33.3(7) Redesignation. The provisions for redesignation as specified in 40 CFR 52.21(g) as amended through November 29, 2005, are adopted by reference.

33.3(8) Stack heights. The provisions for stack heights as specified in 40 CFR 52.21(h) as amended through November 29, 2005, are adopted by reference.

33.3(9) Exemptions. The provisions for allowing exemptions from certain requirements for PSD-subject sources as specified in 40 CFR 52.21(i) as amended through March 6, 2015, are adopted by reference.

33.3(10) Control technology review. The provisions for control technology review as specified in 40 CFR 52.21(j) as amended through November 29, 2005, are adopted by reference.

33.3(11) Source impact analysis. The provisions for a source impact analysis as specified in 40 CFR 52.21(k) as amended through December 9, 2013, are adopted by reference.

33.3(12) Air quality models. The provisions for air quality models as specified in 40 CFR 52.21(l) as amended through November 29, 2005, are adopted by reference.

33.3(13) Air quality analysis. The provisions for an air quality analysis as specified in 40 CFR 52.21(m) as amended through November 29, 2005, are adopted by reference.

33.3(14) Source information. The provisions for providing source information as specified in 40 CFR 52.21(n) as amended through November 29, 2005, are adopted by reference.

33.3(15) Additional impact analyses. The provisions for an additional impact analysis as specified in 40 CFR 52.21(o) as amended through November 29, 2005, are adopted by reference.

33.3(16) Sources impacting federal Class I areas—additional requirements. The provisions for sources impacting federal Class I areas as specified in 40 CFR 51.166(p) as amended through October 20, 2010, are adopted by reference. The following phrases contained in 40 CFR 51.166(p) are not adopted by reference: “the plan may provide that,” “the plan shall provide that,” “the plan shall provide” and “mechanism whereby.”

33.3(17) Public participation.

a. The department shall notify all applicants within 30 days as to the completeness of the application or any deficiency in the application or information submitted. In the event of such a deficiency, the date of receipt of the application shall be the date on which the department received all required information.

b. Within one year after receipt of a complete application, the department shall:

(1) Make a preliminary determination whether construction should be approved, approved with conditions, or disapproved.

(2) Make available in at least one location in each region in which the proposed source would be constructed a copy of all materials the applicant submitted, a copy of the preliminary determination, and a copy or summary of other materials, if any, considered in making the preliminary determination.

(3) Notify the public, by posting on a publicly available website identified by the department, of the application, of the preliminary determination, of the degree of increment consumption that is expected from the source or modification, and of the opportunity for comment at a public hearing as well as written public comment. The electronic notice shall be available for the duration of the public comment period and shall include the notice of public comment, the draft permit(s), information on how to access the administrative record for the draft permit(s) and how to request or attend a public hearing on the draft permit(s). The department may use other means if necessary to ensure adequate notice to the affected public. At least 30 days shall be provided for public comment and for notification of any public hearing.

(4) Send a copy of the notice of public comment to the applicant, to the Administrator and to officials and agencies having cognizance over the location where the proposed construction would occur as follows: any other state or local air pollution control agencies; the chief executives of the city and county where the source would be located; any comprehensive regional land use planning agency; and

any state, federal land manager, or Indian governing body whose lands may be affected by emissions from the source or modification.

(5) Provide opportunity for a public hearing for interested persons to appear and submit written or oral comments on the air quality impact of the source, alternatives to the proposed source or modification, the control technology required, and other appropriate considerations. At least 30 days' notice shall be provided for any public hearing.

(6) Consider all written comments submitted within a time specified in the notice of public comment and all comments received at any public hearing(s) in making a final decision on the approvability of the application. The department shall make all comments available for public inspection at the same locations where the department made available preconstruction information relating to the proposed source or modification.

(7) Make a final determination whether construction should be approved, approved with conditions, or disapproved.

(8) Notify the applicant in writing of the final determination and make such notification available for public inspection at the same locations where the department made available preconstruction information and public comments relating to the proposed source or modification.

c. Reopening of the public comment period.

(1) If comments submitted during the public comment period raise substantial new issues concerning the permit, the department may, at its discretion, take one or more of the following actions:

1. Prepare a new draft permit, appropriately modified;
2. Prepare a revised fact sheet;
3. Prepare a revised fact sheet and reopen the public comment period; or
4. Reopen or extend the public comment period to provide interested persons an opportunity to comment on the comments submitted.

(2) The public notice provided by the department pursuant to this rule shall define the scope of the reopening. Department review of any comments filed during a reopened comment period shall be limited to comments pertaining to the substantial new issues causing the reopening.

33.3(18) Source obligation.

a. Approval to construct shall not relieve any owner or operator of the responsibility to comply fully with applicable provisions of the plan and any other requirements under local, state or federal law.

b. At such time that a particular source or modification becomes a major stationary source or major modification solely by virtue of a relaxation in any enforceable limitation which was established after August 7, 1980, on the capacity of the source or modification otherwise to emit a pollutant, such as a restriction on hours of operation, the requirements of subrules 33.3(10) through 33.3(19) shall apply to the source or modification as though construction had not yet commenced on the source or modification.

c. Any owner or operator who constructs or operates a source or modification not in accordance with the application pursuant to the provisions in rule 567—33.3(455B) or with the terms of any approval to construct, or any owner or operator of a source or modification subject to the provisions in rule 567—33.3(455B) who commences construction after April 15, 1987 (the effective date of Iowa's PSD program), without applying for and receiving department approval, shall be subject to appropriate enforcement action.

d. Approval to construct shall become invalid if construction is not commenced within 18 months after receipt of such approval, if construction is discontinued for a period of 18 months or more, or if construction is not completed within a reasonable time. The department may extend the 18-month period upon a satisfactory showing that an extension is justified. These provisions do not apply to the time between construction of the approved phases of a phased construction project; each phase must commence construction within 18 months of the projected and approved commencement date.

e. Reserved.

f. Except as otherwise provided in subparagraph (8), the following specific provisions shall apply with respect to any regulated NSR pollutant emitted from projects at existing emissions units at a major stationary source, other than projects at a source with a PAL, in circumstances where there is a "reasonable possibility," within the meaning of subparagraph (8), that a project that is not part of

a major modification may result in a significant emissions increase of such pollutant, and the owner or operator elects to use the method for calculating projected actual emissions as specified in subrule 33.3(1), paragraphs “1” through “3” of the definition of “projected actual emissions.”

(1) Before beginning actual construction of the project, the owner or operator shall document and maintain a record of the following information:

1. A description of the project;
2. Identification of the emissions unit(s) whose emissions of a regulated NSR pollutant could be affected by the project; and
3. A description of the applicability test used to determine that the project is not a major modification for any regulated NSR pollutant, including the baseline actual emissions, the projected actual emissions, the amount of emissions excluded under paragraph “3” of the definition of “projected actual emissions” in subrule 33.3(1), an explanation describing why such amount was excluded, and any netting calculations, if applicable.

(2) No less than 30 days before beginning actual construction, the owner or operator shall meet with the department to discuss the owner’s or operator’s determination of projected actual emissions for the project and shall provide to the department a copy of the information specified in paragraph “f.” The owner or operator is not required to obtain a determination from the department regarding the project’s projected actual emissions prior to beginning actual construction.

(3) If the emissions unit is an existing electric utility steam generating unit, before beginning actual construction, the owner or operator shall provide a copy of the information set out in subparagraph (1) to the department. The requirements in subparagraphs (1), (2) and (3) shall not be construed to require the owner or operator of such a unit to obtain any determination from the department before beginning actual construction.

(4) The owner or operator shall:

1. Monitor the emissions of any regulated NSR pollutant that could increase as a result of the project and that is emitted by any emissions unit identified in subparagraph (1);
2. Calculate the annual emissions, in tons per year on a calendar-year basis, for a period of five years following resumption of regular operations and maintain a record of regular operations after the change, or for a period of ten years following resumption of regular operations after the change if the project increases the design capacity or potential to emit of that regulated NSR pollutant at such emissions unit (for purposes of this requirement, “regular” shall be determined by the department on a case-by-case basis); and
3. Maintain a written record containing the information required in this subparagraph.

(5) The written record containing the information required in subparagraph (4) shall be retained by the owner or operator for a period of ten years after the project is completed.

(6) If the unit is an existing electric utility steam generating unit, the owner or operator shall submit a report to the department within 60 days after the end of each year during which records must be generated under subparagraph (4) setting out the unit’s annual emissions during the calendar year that preceded submission of the report.

(7) If the unit is an existing unit other than an electric utility steam generating unit, the owner or operator shall submit a report to the department if the annual emissions, in tons per year, from the project identified in subparagraph (1), exceed the baseline actual emissions, as documented and maintained pursuant to subparagraph (4), by an amount that is “significant” as defined in subrule 33.3(1) for that regulated NSR pollutant, and if such emissions differ from the preconstruction projection as documented and maintained pursuant to subparagraph (4). Such report shall be submitted to the department within 60 days after the end of such year. The report shall contain the following:

1. The name, address and telephone number of the major stationary source;
2. The annual emissions as calculated pursuant to subparagraph (4); and
3. Any other information that the owner or operator wishes to include in the report (e.g., an explanation as to why the emissions differ from the preconstruction projection).

(8) A “reasonable possibility” under this paragraph (paragraph 33.3(18) “f”) occurs when the owner or operator calculates the project to result in either:

1. A projected actual emissions increase of at least 50 percent of the amount that is a “significant emissions increase,” as defined under subrule 33.3(1) (without reference to the amount that is a significant net emissions increase), for the regulated NSR pollutant; or

2. A projected actual emissions increase that, when added to the amount of emissions excluded under subrule 33.3(1), paragraph “3” of the definition of “projected actual emissions,” equals at least 50 percent of the amount that is a “significant emissions increase,” as defined under subrule 33.3(1) (without reference to the amount that is a significant net emissions increase), for the regulated NSR pollutant. For a project for which a reasonable possibility occurs only within the meaning of this numbered paragraph, and not also within the meaning of numbered paragraph “1” of this subparagraph (subparagraph (8)), then the provisions of subparagraphs (3) through (7) do not apply to the project.

g. The owner or operator of the source shall make the information required to be documented and maintained pursuant to paragraph “f” available for review upon request for inspection by the department or the general public pursuant to the requirements for Title V operating permits contained in 567—subrule 22.107(6).

33.3(19) Innovative control technology. The provisions for innovative control technology as specified in 40 CFR 51.166(s) as amended through November 29, 2005, are adopted by reference. The following phrases contained in 40 CFR 51.166(s) are not adopted by reference: “the plan may provide that” and “the plan shall provide that.”

33.3(20) Conditions for permit issuance. Except as explained below, a permit may not be issued to any new “major stationary source” or “major modification” as defined in subrule 33.3(1) that would locate in any area designated as attainment or unclassifiable for any national ambient air quality standard pursuant to Section 107 of the Act, when the source or modification would cause or contribute to a violation of any national ambient air quality standard. A major stationary source or major modification will be considered to cause or contribute to a violation of a national ambient air quality standard when such source or modification would, at a minimum, exceed the following significance levels at any locality that does not or would not meet the applicable national standard:

Pollutant	Averaging Time				
	Annual (µg/m ³)	24 hrs. (µg/m ³)	8 hrs. (µg/m ³)	3 hrs. (µg/m ³)	1 hr. (µg/m ³)
SO ₂	1.0	5	_____	25	_____
PM ₁₀	1.0	5	_____	_____	_____
PM _{2.5}	0.3	1.2	_____	_____	_____
NO ₂	1.0	_____	_____	_____	_____
CO	_____	_____	500	_____	2000

A permit may be granted to a major stationary source or major modification as identified above if the major stationary source or major modification reduces the impact of its emissions upon air quality by obtaining sufficient emissions reductions to compensate for its adverse ambient air impact where the major stationary source or major modification would otherwise contribute to a violation of any national ambient air quality standard. This subrule shall not apply to a major stationary source or major modification with respect to a particular pollutant if the owner or operator demonstrates that the source is located in an area designated under Section 107 of the Act as nonattainment for that pollutant.

33.3(21) Administrative amendments.

a. Upon request for an administrative amendment, the department may take final action on any such request and may incorporate the requested changes without providing notice to the public or to affected states, provided that the department designates any such permit revisions as having been made pursuant to subrule 33.3(21).

b. An administrative amendment is a permit revision that does any of the following:

- (1) Corrects typographical errors;
- (2) Corrects word processing errors;

(3) Identifies a change in name, address or telephone number of any person identified in the permit or provides a similar minor administrative change at the source; or

(4) Allows for a change in ownership or operational control of a source where the department determines that no other change in the permit is necessary, provided that a written agreement that contains a specific date for transfer of permit responsibility, coverage, and liability between the current permittee and the new permittee has been submitted to the department.

33.3(22) Permit rescission. Any permit issued under 40 CFR 52.21 or this chapter or any permit issued under rule 567—22.4(455B) shall remain in effect unless and until it is rescinded. The department will consider requests for rescission that meet the conditions specified under paragraphs “a” and “b” of this subrule. If the department rescinds a permit or a condition in a permit issued under 40 CFR 52.21, this chapter, or rule 567—22.4(455B), the public shall be given adequate notice of the proposed rescission. Posting of an announcement of rescission on a publicly available website identified by the department 60 days prior to the proposed date for rescission shall be considered adequate notice.

a. The department may rescind a permit or a portion of a permit upon request from an owner or operator of a stationary source who holds a permit for a source or modification that was issued:

(1) Under 40 CFR 52.21 as in effect on July 30, 1987, or earlier, provided the application also meets the provisions in paragraph 33.3(22) “b”;

(2) Under this chapter between July 1, 2011, and July 6, 2015, to a source that was classified as a major stationary source under subrule 33.3(1) solely on the basis of potential emissions of greenhouse gases; or

(3) Under this chapter between July 1, 2011, and July 6, 2015, for a modification that was classified as a major modification under subrule 33.3(1) solely on the basis of an increase in emissions of greenhouse gases.

b. If the application for rescission meets the provisions in paragraph “a” of this subrule, the department may rescind a permit if the owner or operator shows that the PSD provisions under 40 CFR 52.21 or this chapter would not apply to the source or modification.

[ARC 8215B, IAB 10/7/09, effective 11/11/09; ARC 9224B, IAB 11/17/10, effective 12/22/10; ARC 9906B, IAB 12/14/11, effective 11/16/11; ARC 0260C, IAB 8/8/12, effective 9/12/12; ARC 0783C, IAB 6/12/13, effective 7/17/13; ARC 1913C, IAB 3/18/15, effective 4/22/15; ARC 2949C, IAB 2/15/17, effective 3/22/17; ARC 3679C, IAB 3/14/18, effective 4/18/18; ARC 5051C, IAB 6/17/20, effective 7/22/20]

567—33.4 to 33.8 Reserved.

567—33.9(455B) Plantwide applicability limitations (PALs). This rule provides an existing major source the option of establishing a plantwide applicability limitation (PAL) on emissions, provided the conditions in this rule are met. The provisions for a PAL as set forth in 40 CFR 52.21(aa) as amended through July 12, 2012, are adopted by reference, except that the term “Administrator” shall mean “the department of natural resources.”

[ARC 0783C, IAB 6/12/13, effective 7/17/13]

567—33.10(455B) Exceptions to adoption by reference. All references to Clean Units and Pollution Control Projects set forth in 40 CFR Sections 52.21 and 51.166 are not adopted by reference.

These rules are intended to implement Iowa Code chapter 455B.

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DIVISION C
WITHDRAWAL, DIVERSION AND STORAGE
OF WATER: WATER RIGHTS ALLOCATION

CHAPTER 50

SCOPE OF DIVISION—DEFINITIONS—FORMS—RULES OF PRACTICE

[Prior to 12/3/86, Water, Air and Waste Management[900]]

567—50.1(455B) Scope of division. The department has jurisdiction over the surface and groundwater of the state to establish and administer a comprehensive program to ensure that the water resources of the state be put to beneficial use to the fullest extent possible, that the waste or unreasonable use, or unreasonable methods of use of water be prevented, and that the conservation and protection of water resources be required with the view to their reasonable and beneficial use in the interest of the people.

Any person who proposes to pump or divert by gravity more than 25,000 gallons of water during a period of 24 hours or less from any source of groundwater or surface water, including streams bordering the state, impound surface water, divert surface runoff into a well, sinkhole or excavation or inject water or any material into a well has a duty to review the thresholds in Chapter 51 and contact the department to resolve any doubt concerning whether a permit is required.

Chapter 51 explains when approval is required for withdrawal, diversion or storage of water. Chapter 52 explains criteria for permitting withdrawal, diversion or storage of water. Chapter 53 sets forth the procedure for designating certain ground and surface water sources as protected sources and explains special criteria and conditions which may be applicable to those sources. Chapter 54 describes procedures and criteria for determining compensation to owners of nonregulated wells for well interference caused by permitted uses.

567—50.2(455B) Definitions. Definitions used in this division of these rules are listed in alphabetical order as follows:

“Adequate groundwater supply” means an aquifer which is capable of providing enough water to satisfy the demands which have been placed on it.

“Administrative resolution” means the settlement of well interference conflicts by the department according to established rules.

“Agricultural drainage well” means a vertical opening to an aquifer or permeable substratum which is constructed by any means including but not limited to drilling, driving, digging, boring, using an auger, jetting, washing, or coring, and which is capable of intercepting or receiving surface or subsurface drainage water from land directly or by a drainage system.

“Agricultural drainage well area” means an area of land where surface or subsurface water drains into an agricultural drainage well directly or through a drainage system connecting to the agricultural drainage well.

“Apparent well interference” means well interference in a nonregulated well resulting from a permitted use is likely but has not been verified.

“Aquifer” means a water-bearing geologic formation (soil or rock) of sufficient volume, porosity, and permeability to be capable of yielding a usable quantity of water to a well or spring.

“Bulletin No. 23” means Technical Bulletin No. 23 entitled “Guidelines for Well Interference Compensation,” March 1986.

“Certified well contractor” means a well contractor who has successfully passed an examination prescribed by the department to determine the applicant’s qualifications to perform well drilling or pump services or both pursuant to 567—Chapter 82.

“Community public water supply” means a system for the provision to the public of piped water for domestic use which has at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

“Compensation” means payment to the owner of a nonregulated well for damages caused by a lowered water level in the well due to withdrawal of water for a permitted use.

“Complainant” means the owner of a nonregulated well who is suspected of being or has been shown to be adversely affected by well interference.

“*Complaint*” means the formal allegation against a permitted water user who is suspected of causing well interference.

“*Confined aquifer*” means an aquifer which contains water under pressure overlain by impermeable formations such as clay or shale. In a well penetrating a confined aquifer, pressure will cause water to rise above the top of the aquifer. If the pressure in a confined aquifer is sufficiently great, water will rise above the ground surface and flow from a well, thus resulting in a “flowing artesian well” or a “naturally flowing well.”

“*Conflict*” means a dispute between a nonregulated well owner and a permitted water user regarding the liability of the permitted user for well interference damages to the nonregulated well.

“*Consumptive use*” means any use of water which involves substantial evaporation, transpiration, incorporation of water into a product or removal of water from a source without return thereto. Consumptive uses include, but are not limited to, irrigation, evaporative cooling, and flooding of wildlife areas by withdrawals or diversions from watercourses or aquifers.

“*Controlled aquifer test*” means a test, as approved by the department, for pumping from a well at a controlled rate for a specified duration while water levels are accurately measured at given frequencies in the pumping well and other nearby wells which use the same aquifer.

“*Designated agricultural drainage well area*” means an agricultural drainage well area in which there is located an anaerobic lagoon or earthen manure storage structure which requires a construction permit under 567—Chapter 65.

“*Domestic use*” means a use of water for human consumption and sanitation and public safety (fire protection).

“*Drainage system*” means tile lines, laterals, surface inlets, or other improvements which are constructed to facilitate the drainage of land.

“*Earthen storage structure*” means an earthen cavity, either covered or uncovered, including but not limited to an anaerobic lagoon or earthen manure storage basin which is used to store manure, sewage, wastewater, industrial waste, or other waste as regulated by the department of natural resources, if stored in a liquid or semiliquid state.

“*General crop*” means hay, corn, soybeans, oats, grain sorghum or wheat.

“*Industrial use*” means a use of water by manufacturing, processing, commercial, and other industrial facilities incidental to providing a product or a service; excluding domestic use, irrigation use, livestock use, nonindustrial power generation use, and recreational and aesthetic use. Examples include but are not limited to manufacturing, food processing, industrial cooling, excavation and processing of rock and gravel products, commercial laundries, cooling of perishables and electrical power generation other than for public consumption.

“*Informal negotiations*” means discussion between a complainant and permittee or applicant regarding settlement of a well interference conflict.

“*Informal settlement*” means a resolution of a well interference conflict by informal negotiations between a complainant and permittee or applicant without formal action by the department.

“*Irrigation use*” means a use of water which is artificially applied to land to aid the growing of general crops and specialty crops.

“*Livestock use*” means a use of water in the production of animals such as for drinking, sanitation and cooling.

“*Nonregulated well*” means a well used to supply water for a nonregulated use (a use of water less than 25,000 gallons per day which is not required to have a water use permit).

“*Permanent storage*” means the volume of water expressed in acre-feet which is stored upstream from a dam or in an impoundment up to the level of the principal outlet works of the structure.

“*Permitted use*” means a use of water in excess of 25,000 gallons per day which requires a water use permit pursuant to these rules and 567—Chapters 51 and 52 and Iowa Code chapter 455B, division III, part 4.

“*Pesticide*” means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating directly or indirectly any insects, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living persons, which the secretary of

agriculture shall declare to be a pest; and (2) any substance intended for use as a plant growth regulator, defoliant, or desiccant.

“Power generation use” means a use of water incidental to the generation of electric power for distribution and sale to the public including process water (e.g., boiler makeup) and water for cooling purposes.

“Protected flow” means the *“established average minimum flow”* defined in Iowa Code section 455B.261.

“Protected source” means a surface water or groundwater source recognized by rule as needing special protection in order to ensure its long-term availability, in terms of either quality or quantity, or both, to preserve the public health and welfare.

“Recreational and aesthetic use” means a use of water which can be curtailed and is not essential for the preservation of life, the general welfare, or the state’s economic base. Examples include but are not limited to flooding of wildlife areas; filling of pools and fountains; nonessential cooling; car washing; street cleaning; washing of other exterior surfaces such as windows and walls; amusement park-type water rides; turf watering such as lawns, golf courses, and athletic fields; and watering of landscape plantings.

“Seven-day, 1-in-10 year low flow (7Q10)” means the minimum average flow expected to occur during a period of seven consecutive days which has an average recurrence interval of once in ten years. The 7Q10 may be calculated for specific seasonal periods of less than one year when appropriate.

“Specialty crop” means all other crops not listed as a general crop, including but not limited to melons, sod farm or seed corn.

“Stream” means a *“watercourse”* other than a lake as defined in Iowa Code section 455B.261.

“Stream bordering the state” means those reaches of the Missouri, Mississippi, Des Moines, and Big Sioux rivers that serve as a state boundary.

“Sufficient water supply” means a nonregulated well which is capable of providing enough water for the nonregulated use.

“Surface water” means water occurring on the surface of the ground.

“Surface water intake” means an artificial opening to a drain tile which drains into an agricultural drainage well, if the artificial opening allows surface water to enter the drain tile without filtration through the soil profile.

“Suspect permittee” means a party possessing a water use permit when the permitted use is suspected of causing well interference in a nonregulated well.

“Test pumping” means a controlled aquifer test for verification of well interference using the existing wells and pumping systems of the complainant and suspect permittee.

“Verified well interference” means well interference which has been proven by test pumping or with other substantial evidence to have caused or will cause a nonregulated well to be unable to maintain a sufficient water supply.

“Water use reduction plan” means a program that establishes numeric water reduction goals (e.g., percent or volume of water per day) on a short-term time frame through either voluntary or mandatory conservation regulatory requirements (e.g., plumbing codes, sprinkling ordinances, et al.) for each customer category (residential, commercial, industrial, landscape irrigation, agricultural, recreational, or other). Such a plan shall include a mechanism for evaluating the system’s unaccounted-for water (water audit or the equivalent). An industrial permittee water use reduction plan shall examine reduction of the use of water in heat transfer, use of water in materials transfer, use of water for washing, and use of water as an incorporated ingredient. Each customer category or use category should be evaluated by the permittee. The permittee will then determine how to meet the water reduction goals.

“Well interference” means the lowering of water level in a well caused by the withdrawal of water at another location (usually a nearby well).

[ARC 2053C, IAB 7/8/15, effective 8/12/15]

567—50.3(17A,455B) Forms for withdrawal, diversion or storage of water.

50.3(1) Application forms. The following application forms are currently in use:

Form 16: Application for a New Water Use Permit or to Modify an Existing Water Use Permit. 542-3106.

Form 18: Application for Permit to Store Water for Beneficial Use. 542-3109.

Form 20: Registration of Minor Nonrecurring Use of Water. 542-3112.

Form 542-1470: Water Supply Section Water Use Permit Renewal.

Form 542-1539: Application for Use of an Agricultural Drainage Well.

50.3(2) *Supplementary information forms.* The following forms are used to obtain additional information to supplement various types of applications:

Form 21: Survey of Land Owners and Occupants. 542-3113.

Form 22: Well Inventory Form. 542-3114.

Form 122: Water Well Inspection Report.

50.3(3) *Reporting form.* The following form is for reporting permitted activities:

Form 23: Report of Water Use by all Regulated Users. 542-3115.

567—50.4(17A,455B) How to request a permit.

50.4(1) *Application form.*

a. Application for approval of a new withdrawal, diversion or storage of water unrelated to the use of an agricultural drainage well. For withdrawals, diversions, or storage of water unrelated to the use of an agricultural drainage well, a request for a new permit as distinguished from modification or renewal of an existing permit shall be made on Form 16 (542-3106). An application form must be submitted by or on behalf of the owner, lessee, easement holder or option holder of the area where the water is to be withdrawn, diverted or stored, and used. An application must be accompanied by a map portraying the points of withdrawal or diversion and storage, and the land on which water is to be used oriented as to section, township, and range. One application normally will be adequate for all uses on contiguous tracts of land. Tracts of land involved in the same operation separated only by roads or railroads will be deemed contiguous tracts.

b. Application for diversion of water related to the use of an agricultural drainage well. An application for the diversion of water and any other materials to an aquifer related to the use of an agricultural drainage well shall be made on a form obtained from the department and be submitted by or on behalf of such owners, lessees, easement holders, or option holders of all lands within the agricultural drainage well area. If the agricultural drainage well is part of a legally organized drainage district, the drainage district shall be a joint applicant. Applications for permits for diversions related to the use of an agricultural drainage well that existed prior to February 18, 1998, shall be made by July 1, 1999, with the exception of agricultural drainage wells that must be closed to comply with the provisions of 1997 Iowa Acts, Senate File 473. An application will not have to be filed for wells in a designated agricultural drainage well area which must be closed by December 31, 1999. In addition, the department may grant up to a six-month delay in the application date for owners of agricultural drainage wells where it can be shown there is a reasonable expectation that the agricultural drainage well will be voluntarily closed by December 31, 1999.

c. Application for modification or renewal of a permit. A request for renewal of a permit should be submitted on Form 542-1470. A request to modify an existing permit shall be made on Form 16 (542-3106) and must include an explanation of the necessity for the modification.

d. Where to submit application. Rescinded IAB 6/7/06, effective 7/12/06.

50.4(2) *Fees.*

a. Application fee. An application to the department for a new permit, modification of an existing permit, or registration of a minor nonrecurring use of water must be accompanied with the fee listed in the table below. These fees are nonrefundable and are not transferable. For any single application, if more than one fee in the table below applies, only the higher fee is required. The fees become effective on July 1, 2009.

Application Description	Form	Fees, in dollars
(1) To apply for a new permit to withdraw or divert water	16 (542-3106)	\$350
(2) To renew an existing permit	542-1470	\$0
(3) To modify an existing permit to either add a new source or increase the amount or rate of water withdrawn or diverted from a source or sources	16 (542-3106)	\$350
(4) To modify the conditions of an existing permit which are not described in Item 3 of this table (see above)	16 (542-3106)	\$0
(5) To apply for an aquifer storage and recovery permit or a protected source designation	N/A	\$700
(6) To apply for a permit to store water	18 (542-3109)	\$75
(7) To register a minor nonrecurring use of water	20 (542-3112)	\$75

b. Annual permit fee. In addition to the application fee, there is an annual permit fee for a water use permit or an aquifer storage and recovery permit. The annual fee shall be based on the number of active permits. Each permit holder shall pay the same annual fee. The fee will not be prorated and is nonrefundable. The annual permit fee is due December 1 of each year, beginning with December 1, 2009. The department will provide an annual fee notice to each permittee at least 60 days prior to the fee due date. An additional fee of \$100 will be imposed if the fee is not received by December 1. Failure to remit the fee by January 1 may result in the cancellation of the permit.

(1) There is no annual fee for a water storage permit (see (6) of table, paragraph 50.4(2) “a”) or for a minor nonrecurring water use registration (see (7) of table, paragraph 50.4(2) “a”).

(2) The annual fee shall be based on the costs for administering the water use permitting program for the previous calendar years and on the anticipated expenses for succeeding fiscal years. The department will review the annual permit fee each year and adjust the fee as necessary to cover all reasonable costs required to develop and administer the water use permitting program. Permit holders that have paid an application fee after December 1, but prior to November 30, will not be required to pay an annual fee until December 1 of the following year. If an applicant remits an annual fee for the 12-month period beginning December 1 and then later submits an application fee for a permit modification, the applicant will be refunded the lesser of the fees. The department shall request commission approval of the amount of the annual fee no later than September 30 of each year.

50.4(3) Supporting information required for complete application. An application shall not be considered complete until the fee specified in this rule and all supporting information requested under 567—50.6(17A,455B) have been submitted by the applicant or agents of the applicant.

[ARC 7694B, IAB 4/8/09, effective 5/13/09; ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—50.5(455B) Initial screening of applications.

50.5(1) General procedure. Each application upon receipt shall be promptly evaluated by the department to determine whether adequate information is available to review the project. The department shall then advise the applicant of additional information required to review the project.

50.5(2) Application to withdraw groundwater. Evaluation of the potential effects of a proposed withdrawal of groundwater requires review of available hydrogeological information. The department may require additional supporting hydrogeological information, which the applicant is responsible for providing.

567—50.6(17A,455B) Supporting information. Applicants shall submit supporting information which is reasonably required to assist the department in conducting the investigation of an application required by Iowa Code sections 455B.264 and 455B.281 and in determining whether granting of a permit would be consistent with the policies and principles of beneficial use set forth in Iowa Code section 455B.262. Certain supporting information requirements are described in this rule. This description is intended to identify frequently required information. The department may require additional information relative to the permit application.

50.6(1) Application for permit to withdraw groundwater.

a. Identification of source and effects of pumping. An applicant shall be required to submit information needed by the department to identify the aquifer(s) from which withdrawals of water are proposed, predict the effects of pumping with a reasonable degree of confidence, and determine any permit conditions for well interference pursuant to 567—Chapter 54. At many locations the only reliable methods to determine the availability of a water source of adequate quantity and quality and to predict the effects of pumping require test drilling, yield test pumping, and a controlled aquifer test with measurements in one or more observation wells conducted with prior approval in a manner that is acceptable to the department. The applicant shall be required to perform each of these exploratory operations to the extent necessary for the department to obtain information from which to determine whether a permit should be granted and to identify conditions which should be imposed in any permit granted. The following requirements apply to exploratory drilling and test pumping.

(1) Test drilling. In cases where test drilling is needed for geological information relevant to the application, the applicant is responsible for employing a driller who will collect, bag and properly label cutting samples at each five-foot interval and at each apparent change in geological formation from a test hole or production well hole at least the approximate depth of the proposed production well. The cutting samples must be saved for collection in sample bags provided by the Iowa geological survey (IGS). The samples shall be submitted to IGS and be accompanied by a driller's log showing the location and total depth of the hole and a description of the materials encountered at successive intervals.

(2) Yield testing. An applicant shall be required to construct a well and test pump it for yield to the extent necessary to determine whether water is available at the applicant's proposed rate of withdrawal from the proposed source. A written registration from the department is required before any yield test in which more than 25,000 gallons will be withdrawn in a period of 24 hours or less (see 567—subrule 51.6(5)).

(3) Controlled aquifer test with supervision. An applicant shall be required to conduct a controlled aquifer test with supervision by a certified well contractor, licensed professional engineer or other designee of the department as a condition of obtaining a water permit if the department finds an aquifer test necessary to determine the effects which the proposed withdrawal has on other water uses. The applicant may be required to construct, develop, and maintain adequate observation wells for use in an aquifer test and for subsequent water level measurements or water quality monitoring. An applicant shall be responsible for obtaining a registration for an aquifer test as provided in 567—subrule 51.6(5).

b. Cooperation in obtaining information about surrounding wells. An applicant who requests a permit authorizing withdrawals of groundwater from a well or reservoir may be required to assist the department in conducting an inventory of nearby wells within a designated radius of the proposed site. The need for an inventory and the appropriate radius will be determined after considering the known characteristics of the aquifer which the applicant proposes as a source of water and the rate and amount of the proposed withdrawals. The department shall provide a map specifying the area within which an inventory is proposed and forms specifying the information to be gathered in the inventory. The department shall also provide to the applicant a description of regulated uses within the inventory area. The applicant shall make a good faith effort to assist the department in obtaining available information from public records to identify landowners and occupants and from drilling contractors or pump installers identified by a landowner or occupant responding to the inventory.

50.6(2) *Application for an irrigation permit.* An applicant who proposes to irrigate crops on land which includes soils more erodible than Capability Subclass IIe as defined by the U.S.D.A. Natural Resources Conservation Service (NRCS), or slopes greater than 6 percent where a modern NRCS Soil Survey is not available, shall submit a soil conservation plan prepared with the assistance of the NRCS for the land in which crop irrigation is proposed. The plan shall be accompanied by the applicant's written explanation of how operation of the proposed irrigation system will be compatible with the conservation plan.

50.6(3) *Application for permit to dewater a rock quarry.* Iowa Code section 455B.268 and 567—Chapter 51 require that a permit be obtained before diverting water or material from the surface directly into any underground watercourse or basin. When the department investigates an application for a permit to pump water for dewatering of a quarry excavated in carbonate rock, the department

shall consider the potential for pollution of an underground watercourse or basin from drainage of surface water into the quarry. If available information, including topographic and subsurface geological information, supports a finding that drainage of surface water into the quarry would constitute a violation of the permit requirement in Iowa Code section 455B.268 and might cause pollution of an underground watercourse or basin if not controlled, then the department shall require that the applicant either request a permit to authorize a drainage of surface water into the quarry, or construct and maintain a means of controlling surface water which would otherwise drain into the quarry. Examples of suitable methods of controlling surface drainage are low berms or artificial drainage ways constructed as needed to reduce runoff of surface water from adjacent land into the quarry.

50.6(4) *Application for permit to divert water into an aquifer not related to the use of an agricultural drainage well.* An applicant for a permit to divert water or any other material from the surface into an aquifer not related to the use of an agricultural drainage well shall submit information showing that the requested diversion will not alter the quality of the aquifer.

50.6(5) *Application for uses that were nonregulated prior to July 1, 1985.* Rescinded IAB 6/7/06, effective 7/12/06.

50.6(6) *Applications for a permit to withdraw water from a protected water source.* An applicant for a permit to withdraw water from a protected water source designated in rule 567—53.7(455B) may be required to provide specific information to support the application as required by rule 567—53.5(455B) or rule 567—53.7(455B).

50.6(7) *Application for permit to divert water into an aquifer related to the use of an agricultural drainage well.* An applicant for a permit to divert water or any other material into an aquifer by means of an agricultural drainage well shall submit the following information. The locations of the features as listed below shall be shown on a map drawn to scale submitted with the application.

a. Location of the agricultural drainage well to at least the nearest quarter-quarter section, township and range.

b. Diameter and depth of the agricultural drainage well, if known.

c. Description and ownership of the lands which are drained by the agricultural drainage well and the associated drainage system.

d. Location of tiles which drain to the agricultural drainage well, if known, and the location of any existing surface water intakes.

e. The location and description of any earthen storage structures, confinement feeding operations, or open feedlots within the agricultural drainage well area.

f. Information regarding any known connections between the agricultural drainage well or its drainage system and wastewater disposal or storage systems such as septic tanks and the location of such connections.

g. The nature and extent of any agreements between the well owner and adjacent landowners who have lands which are drained by the agricultural drainage well and associated tile drainage system.

h. Any available information regarding the economic and physical feasibility of closing the agricultural drainage well.

[ARC 4426C, IAB 5/8/19, effective 6/12/19]

567—50.7(17A,455B) Review of complete applications.

50.7(1) *Order of processing.* In general, complete applications including all requested supporting information shall be reviewed in the order that complete information is received. However, when there are a large number of pending applications, which precludes the department from promptly processing all applications, the department may expedite review of a particular application out of order if the completed application and supporting documents were submitted at the earliest practicable time and any of the following conditions exist:

a. Relatively little staff review time (generally less than four hours) is required and delay will cause the applicant hardship;

b. The applicant can demonstrate that a delay in the permit will result in a substantial cost increase of a large project;

c. Prompt review of the permit would result in earlier completion of a project that conveys a significant public benefit;

d. The need for a permit is the result of an unforeseen emergency or catastrophic event; or

e. A permit is needed to complete a project that will abate or prevent an imminent threat to the public health and welfare.

50.7(2) Summary report of application review. Before an initial decision is issued on an application, personnel assigned to review an application shall prepare a summary report which shall state whether the withdrawal, diversion, or use of water as described in the complete application conforms to relevant criteria. The report shall identify the information used to determine the potential for a proposed use of water to adversely affect other water users. For an application to withdraw groundwater, the report shall describe the effects on water levels anticipated to occur from the proposed use; indicate if verified well interference has been found; and provide options for resolving any verified well interference in accordance with 567—Chapter 54.

50.7(3) Public notice of recommendation to issue permit.

a. *New permits and modifications of permits.*

Prior to the issuance of a permit to withdraw, divert or inject water, the department shall publish a notice of recommendation to grant a permit. The notice shall summarize the application and the recommendations in the summary report. The notice shall allow 20 days to request a copy of the summary report and submit comments on the report. The department may extend the comment period upon request for good cause. The notice may be published in a newspaper circulated in the locality of the proposed water source, or the department may use other methods of publishing the notice to ensure adequate notice to the affected public. The notice shall be sent to any person who has requested a copy of the notice concerning the particular water use under consideration.

b. *Permit renewals.* The notice provisions of paragraph “a” of this subrule shall apply to requests for permit renewals except that the department need not publish notice of recommendation to grant a renewal permit which does not involve modification of permit conditions.

50.7(4) Notice to the applicant that proposed withdrawal, diversion or use of water does not conform to criteria. If the application review discloses that the proposed withdrawal, diversion or use of water violates one or more criteria and the application should therefore be disapproved, or approved only subject to special conditions to which the applicant has not agreed, the department shall notify the applicant and, when practical, suggest appropriate project modifications. The department shall offer the applicant an opportunity to submit comments before an initial decision is made.

50.7(5) Applications for uses that were nonregulated prior to July 1, 1985. Rescinded IAB 6/7/06, effective 7/12/06.

[ARC 5052C, IAB 6/17/20, effective 7/22/20]

567—50.8(17A,455B) Initial decision by the department.

50.8(1) Form of decision. The initial decision on an application shall be a permit or disapproval issued by the department. Each permit shall include appropriate standard and special conditions consistent with Iowa Code sections 455B.261 to 455B.274 and 455B.281 and 567—Chapters 52 to 54. The decision may incorporate by reference and attachment the summary report described in 50.7(2). Each decision shall include the following:

a. Determinations as to whether the project satisfies all relevant criteria not addressed in an attached summary report.

b. An explanation of the purpose for imposing each special condition.

c. Explanation of consideration given to all comments submitted pursuant to 50.7(3) and 50.7(4) unless the comments are adequately addressed in the attached summary report.

50.8(2) Notice of initial decision. Copies of the initial decision shall be mailed to the applicant, any person who commented pursuant to 50.7(3), and any other person who has requested a copy of the decision. The decision shall be accompanied by a certification of the date of mailing. An initial decision becomes the final decision of the department unless a timely notice of appeal is filed in accordance

with 567—50.9(17A,455B). The final decision may be filed with the appropriate county recorder to give constructive notice to future landowners of any conditions or requirements imposed by the final decision.

567—50.9(17A,455B) Appeal of initial decision. Any person aggrieved by an initial decision issued under 567—50.8(17A,455B) may file a notice of appeal with the director. The notice of appeal must be filed within 30 days following the certified date of mailing of the decision unless the appellant shows good cause for failure to receive actual notice and file within the allowed time. The form of the notice of appeal and appeal procedures are governed by 567—Chapter 7. The department shall mail a copy of the notice of appeal to each person who commented on the application. If the appeal is from denial of a permit and a notice of recommendation to grant a permit was not published, the department shall publish the notice of commencement of a contested case and provide an opportunity for interested people to seek intervention in the contested case.

These rules are intended to implement Iowa Code sections 17A.3, 455B.105, 455B.171, 455B.262, 455B.264 to 455B.274, 455B.278, and 455B.281 and chapter 460.

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¹ At its meeting held 2/9/98, the Administrative Rules Review Committee delayed 50.2, eight definitions, 50.3(1), 50.4, 50.6(4), 50.6(7), 50.7(2), 50.7(4) and 50.8(2) until adjournment of the 1998 Session of the General Assembly.

NATURAL RESOURCE COMMISSION[571]

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[Prior to 12/31/86, Conservation Commission[290] Ch 30]

571—40.1(462A) Restricted areas. All vessels, except authorized emergency vessels, shall be operated in compliance with, and all persons engaged in water recreation activities, shall obey restrictions with posted areas marked with a uniform waterway buoy or official signs adopted by the natural resource commission.

571—40.2(462A) Uniform buoy system. All buoys placed shall be those of the uniform waterway marking system adopted by the natural resource commission and shall be constructed, placed, and maintained in accordance with Iowa Code chapter 462A and Iowa Administrative Code 571—Chapters 40 and 41.

571—40.3(462A) Commission approval. The placement of buoys or official signs that restrict speed and distance or involve special zoning restrictions shall be approved by the natural resource commission.

571—40.4(462A) Right for aggrieved party to appeal. Any finding or establishment of areas involving special speed and distance or zoning restrictions by the natural resource commission may be appealed by aggrieved party upon written notice. A hearing thereon shall be held by the natural resource commission within 30 days thereafter.

571—40.5(462A) Rathbun Lake, Appanoose County—zoned areas.

40.5(1) Areas may be specifically designated for swimming and wading.

40.5(2) Areas may be designated restricted speed areas.

571—40.6(462A) Red Rock Lake, Marion County—zoned areas.

40.6(1) Areas may be specifically designated for swimming and wading.

40.6(2) Areas may be designated restricted speed areas.

40.6(3) Areas may be designated as “no anchoring” areas.

571—40.7(462A) Coralville Lake, Johnson County—zoned areas.

40.7(1) Areas may be specifically designated for swimming and wading.

40.7(2) Areas may be designated restricted speed areas.

571—40.8(462A) Saylorville Lake, Polk County—zoned areas.

40.8(1) Areas may be specifically designated for swimming and wading.

40.8(2) Areas may be designated restricted speed areas.

571—40.9(462A) Lake Odessa in Louisa County.

40.9(1) Areas may be designated restricted speed areas.

40.9(2) All motorboats, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour year around, on that portion of Lake Odessa known as the Sand Run Chute, lying south of the main lake to a point 100 yards south of the Sand Run Chute boat ramp.

40.9(3) All motorboats, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour year around, on those portions of Lake Odessa known as the lateral ditch, between the main lake and Bebee Pond, and on the channel between Yankee Chute and Beaver Pond.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.10(462A) Mississippi River lock and dam safety zone. A safety zone is hereby established in Iowa waters above and below all navigation lock and dam structures on the Mississippi River between the Iowa-Minnesota border and the Iowa-Missouri border. The established zone shall be 600 feet upstream and 150 feet downstream from the roller gate or tainter gate section of the structure.

40.10(1) The safety zone does not include the area directly above and below the navigation lock structure.

40.10(2) The safety zone does not include the area directly above and below the solid fill portion of the dam and structure.

40.10(3) The safety zone shall be recognized by the state of Iowa only when plainly marked as follows:

- a. Upstream signs worded—Restricted area keep 600 feet from dam.
- b. Downstream signs worded—Restricted area keep 150 feet from dam.
- c. Flashing red lights will be used to make the outer limits of the restricted areas.

40.10(4) No boat or vessel of any type, except authorized vessels, shall enter the established safety zones recognized by the state of Iowa as described in this rule.

571—40.11(462A) Joyce Slough Area. The Joyce Slough Area, a portion of the Mississippi River within the city of Clinton, Iowa, is hereby zoned to be a harbor area and vessels traveling therein shall not travel at speeds in excess of five miles per hour.

571—40.12(462A) Swan Slough, Camanche, Iowa. A restricted speed zone of not greater than 5 miles per hour is hereby established in all or part of the main channel of Swan Slough (Mississippi River mile 510.2 to 511.3), Camanche, Iowa, as designated by buoys.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.13(462A) Massey Slough. The operation of vessels in Massey Slough of the Mississippi River at Massey Station, Dubuque County, Iowa, extending from a northerly to southerly direction from the upper end to the lower end of the slough, encompassing the water in Section 14, Township 88N, Range 3E of the 5th P.M., tract number NFIA-26M, is restricted as follows:

40.13(1) All boats underway must maintain a speed of less than five miles per hour in said waters.

40.13(2) Reserved.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.14(462A) Black Hawk County waters. Operation of vessels in Black Hawk County on the Cedar River and any connected backwaters shall be governed by this departmental rule as well as all applicable state laws and regulations.

40.14(1) No vessel, except authorized emergency vessels, shall be operated in marked areas at a speed greater than the limit designated by buoys, signs, or other approved uniform waterway marking devices marking the area.

40.14(2) All vessels, except authorized emergency vessels, shall be operated at a speed not greater than 5 miles per hour when within 600 feet of the Franklin Street bridge. This 600-foot zone shall be designated by buoys, signs, or other approved uniform waterway marking devices.

40.14(3) No vessel shall tow skiers, surfboard riders, or other towable devices within the zone established by 40.14(2).

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.15(462A) Mitchell County waters. Operation of vessels in Mitchell County is restricted to speeds not greater than 5 miles per hour where a speed zone is designated by buoys on the following impounded waters:

Cedar River from Mitchell Dam, thence upriver to the County “S” bridge.

Cedar River from the St. Ansgar Mill Dam, thence upriver to the Newberg Bridge crossing Highway 105.

Cedar River from the Otranto Dam upriver to the Great Western Railway Bridge crossing the Cedar River.

The Stacyville Pool, on the Little Cedar River at Stacyville, Iowa.

40.15(1) Water recreation activities as restricted within posted areas which are marked with approved buoys shall be obeyed.

40.15(2) Reserved.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.16(462A) Maquoketa River. Operation of vessels of the impoundment of the Maquoketa River in Delaware County, Iowa, extending westerly and northerly from the line between Sections 29 and 30 in Delhi Township in said county, to the line between Sections 10 and 15 in Milo Township in said county which impoundment is sometimes known and referred to as Hartwick Lake or Lake Delhi.

40.16(1) Water recreation activity restrictions shall be obeyed, including restrictions within posted areas which are marked with approved buoys.

40.16(2) No motorboat shall be operated at speeds greater than ten miles per hour at any time between the hours from one hour after sunset to one hour before sunrise.

571—40.17(462A) Zoning of off-channel waters of the Wapsipinicon River in Pinicon Ridge Park in Linn County. No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area designated by regulatory buoys or signs on the off-channel waters of the Wapsipinicon River above the dam at Central City, Linn County, Iowa.

The zoned area will be the off-channel waters created in and adjacent to the developed recreation areas of the Pinicon Ridge Park on the west and south bank of the Wapsipinicon River above the dam at Central City, Linn County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.18(462A) Speed restrictions on Lake Manawa. No motorboat shall be operated at a speed greater than five miles per hour within the zoned areas 300 feet from shore around Lake Manawa in Pottawattamie County.

571—40.19(462A) Zoning of Little Wall Lake. No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area designated by regulatory buoys on Little Wall Lake in Hamilton County.

The zoned area will not exceed approximately 20 acres in the northeast portion of the lake identified by a line from a point on the high-water mark approximately 296.6 feet west of the southeast corner of the southwest quarter of Section 10, Township 86 North, Range 24 West; thence northwest to the high-water mark which is 775 feet south and 319 feet west of the northeast corner of the northwest quarter of the southwest quarter of Section 10, Township 86 North, Range 24 West.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.20(462A) Lake Icaria, Adams County—watercraft use. Motorboats of outboard or inboard-outdrive type shall be permitted on Lake Icaria. The following rules shall govern vessel operation on Lake Icaria in Adams County.

40.20(1) All vessels shall be operated at a speed not greater than 5 miles per hour when within 50 feet of another vessel which is not underway or is operating at a no-wake speed.

40.20(2) Zoned areas.

a. No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by the use of buoys or signs in accordance with 571—Chapter 41.

b. No motorboats, except authorized emergency vessels, shall be operated in marked bay areas at a speed greater than the limit designated by buoys or signs marking said bay. Said buoys or signs shall be in accordance with 571—Chapter 41.

c. No motorboats, except authorized emergency vessels, shall be operated in restricted speed areas between the nearest shore and a line designated by uniform marker buoys or signs at a speed greater than the limit designated on the buoys or signs marking the area. Such zoned areas shall be not less than 50 feet nor more than 400 feet from shore. Said buoys or signs shall be in accordance with 571—Chapter 41.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.21(462A) Zoning of the Des Moines River. Vessel operation on the Des Moines River from its confluence with the Mississippi River in Lee County to the northerly meander lines of both the East and West Branches, shall be governed by this departmental rule as well as all applicable state laws and regulations.

40.21(1) No vessel, except authorized emergency vessels, shall be operated in marked areas at a speed greater than the limit designated by buoys marking said areas.

40.21(2) No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by the use of buoys.

571—40.22(462A) Upper Gar Lake, Dickinson County. Operation of vessels on Upper Gar Lake is restricted to a speed not greater than 5 miles per hour between the Henshaw Bridge at the north end of Upper Gar and south end of East Lake and the Old Sawmill Bridge at the south end of Upper Gar and the north end of Minnewashta.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.23(462A) Zoning of the Mississippi River, Guttenberg river mile 616, Clayton County.

40.23(1) All vessels operated between the ice dike and Bussey Lake access shall be operated at a speed not greater than 5 miles per hour.

40.23(2) The city will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.24(462A) Mt. Ayr City Lake (Loch Ayr). A motorboat shall not be operated within 100 feet of shore at a speed greater than 5 miles per hour.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.25(462A) Iowa River in Iowa City, Johnson County. No person shall operate any vessel towing persons on water skis, surfboards, or similar devices on the Iowa River in the area bounded by the Coralville Mill Dam and the Burlington Street Dam, except during regattas, races, marine parades, tournaments, or exhibitions authorized by the natural resource commission to be held in such area.

571—40.26(462A) Zoning of the Mississippi River, Dubuque, Dubuque County.

40.26(1) All vessels shall be limited to no more than five miles per hour in Lake Peosta Cut south and east of the Hawthorn Street municipal boat launching ramp.

40.26(2) A restricted speed zone of no more than 5 miles per hour is established in the vicinity of Chaplain Schmitt Memorial Island in proximity to the Schmitt Island municipal launching ramp and in waters adjacent to the southerly shoreline in the area of the Dubuque Yacht Basin.

40.26(3) A restricted speed zone of five miles per hour for the northern portion of Shawondassee Slough. Marker buoys shall be placed at a point approximately 750 feet upstream from the existing speed zone.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.27(462A) Zoning Harpers Slough, Harpers Ferry, Allamakee County.

40.27(1) All vessels operated in Harpers Slough between a point 200 feet above the state ramp and 200 feet out from the west shore and extending 550 feet downstream from a point known as Sandy Point Road Dead-End shall operate at a speed not greater than 5 miles per hour.

40.27(2) The city of Harpers Ferry will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10; ARC 0111C, IAB 5/2/12, effective 4/13/12]

571—40.28(462A) Black Hawk Lake, Sac County—zoned areas.

40.28(1) No motorboat shall be operated at a speed greater than 5 miles per hour within the zoned area marked by the regulatory buoys. The zoned area shall be the area commonly known as Town Bay on the northwest corner of Black Hawk Lake in Sac County.

40.28(2) Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.29(462A) Speed and other restrictions on Brown's Lake, Woodbury County. All vessels shall be operated at a speed not greater than 5 miles per hour within the two zoned areas designated by regulatory buoys or other approved uniform waterway markers.

40.29(1) Zone 1. Zone 1 shall extend 570 yards from the boat ramp east to the regulatory buoys and 150 yards west from the boat ramp.

40.29(2) Zone 2. Zone 2 shall begin at the regulatory buoys located at the 24-inch steel pipe and shall extend west.

40.29(3) Swimming. Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.30(462A) Speed and other restrictions on Snyder Bend Lake, Woodbury County. All vessels shall be operated at a speed not greater than 5 miles per hour within the zoned area 400 yards from the boat ramp south to the regulatory sign and buoys.

Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.31(462A) Speed restrictions on East Okoboji and West Okoboji Lakes in Dickinson County. No motorboat shall be operated at a speed greater than 5 miles per hour within the three zoned areas designated by regulatory buoys on East Okoboji and West Okoboji Lakes in Dickinson County.

40.31(1) Zone 1. Zone 1 shall be a line from the east side of Givens Point to the south end of Arnolds Park City Beach on West Okoboji. Also, a line 150 yards east from the north end of the railroad trestle bridge at Clair Wilson State Park south to the shoreline of East Okoboji.

40.31(2) Zone 2. Zone 2 shall be the area which is 300 feet north of the area commonly known as the Narrows on East Okoboji and 200 feet south of the area commonly known as the Narrows on East Okoboji.

40.31(3) Zone 3. Zone 3 shall be the area 50 feet east of the bridge between East Okoboji and Upper Gar on the East Okoboji side running in a northwesterly direction toward the end of the island from Gingles Point then west toward the shoreline.

40.31(4) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.31(5) The following areas are zoned 5 miles per hour on West Okoboji.

a. Zone 1. Zone 1 shall be the area commonly known as Okoboji Harbor at the northwest corner of West Okoboji.

b. Zone 2. Zone 2 shall be the area commonly known as the canals in the city of Wahpeton including Turtle Lake.

c. Zone 3. Zone 3 shall be the area commonly known as Lazy Lagoon located in the Triboji Area on West Okoboji.

d. Zone 4. Zone 4 shall be the area commonly known as Little Millers Bay. The zone shall start at Pinkies Point and extend southeasterly (160 degrees) approximately 370 yards until bisecting the southern shoreline of Little Millers Bay.

e. Zone 5. Zone 5 shall be the area commonly known as Little Emmerson Bay. The zone shall start at Breezy Point and extend southwesterly (235 degrees) approximately 330 yards until bisecting the west shoreline of Little Emmerson Bay.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.32(462A) Spirit Lake, Dickinson County—zoned areas.

40.32(1) Areas may be specifically designated for swimming by the use of regulatory buoys.

40.32(2) The following areas are zoned 5 miles per hour on Spirit Lake, Dickinson County:

a. Zone 1 shall be the area commonly known as Templar Park Lagoon located midlake on the west shore of Spirit Lake.

b. Reserved.

571—40.33(462A) Speed restrictions on the Mississippi River, Jackson County, at Spruce Creek County Park. No motorboat shall operate at a speed to exceed 5 miles per hour within the area designated by buoys or other approved uniform waterway markers, beginning at the entrance of Spruce Creek harbor and extending southeast 550 feet and extending east 150 feet from shore. The Jackson County conservation board will designate the speed zone with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.34(462A) Speed restrictions on the Mississippi River, Jackson County, at the city of Sabula. No motorboat shall operate at a speed to exceed five miles per hour within the four zoned areas designated by buoys or other approved uniform waterway markers.

40.34(1) Zone 1. Zone 1 shall extend 200 feet from shore and begin at a point 250 feet upstream of the north Sabula city boat ramp and ending at a point downstream where Bank Street intersects the river bank.

40.34(2) Zone 2. Zone 2 shall extend 200 feet from shore and extend 100 feet upstream and 100 feet downstream from the entrance to the Island City Harbor.

40.34(3) Zone 3. Zone 3 shall extend 200 feet into South Sabula Lake from the county boat ramp and 100 feet to the west of the ramp and 600 feet to the east of the ramp.

40.34(4) Zone 4. Zone 4 shall extend 200 feet in all directions beginning at the center of the “cut” into Lower Sabula Lake.

The city of Sabula shall designate the speed zones with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.35(462A) Speed restrictions on the Greene Impoundment of the Shell Rock River. No motorboat shall be operated at a speed exceeding five miles per hour in the two zoned areas of the Greene Impoundment designated by buoys or other approved uniform waterway markers. The first zoned area extends from the dam in the city of Greene, upstream approximately one-quarter mile to the north boundary of the city park in which the lower boat ramp is located. The second zoned area extends from the county bridge over the Shell Rock River on the north side of section 28 of Union Township in Floyd County, downstream approximately one-quarter mile to the south boundary of Gates Bridge County Park. The city of Greene and Floyd County shall designate their respective speed zones with uniform waterway markers (buoys) approved by the natural resource commission.

571—40.36(462A) Zoning of the Iowa River, Iowa Falls, Hardin County.

40.36(1) All vessels operated in a designated zone between the River Street Bridge and the dock at Dougan’s Landing shall be operated at a speed not greater than 5 miles per hour.

40.36(2) The city of Iowa Falls shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

40.36(3) All vessels operated in a designated zone beginning at the west property boundary and ending at the east property boundary of the Scenic City Empress Boat Club property located at 1113 Union Street shall be operated at a no-wake speed. The zone shall not extend more than 75 feet into the Iowa River channel.

40.36(4) The Scenic City Empress Boat Club shall designate and maintain the no-wake zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10; ARC 3931C, IAB 8/1/18, effective 9/5/18]

571—40.37(462A) Zoning of Crystal Lake. No motorboat shall be operated at a speed greater than 5 miles per hour within the 25-acre zoned area designated by regulatory buoys on Crystal Lake in Hancock County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.38(462A) Five Island Lake, Palo Alto County.

- 40.38(1)** Areas may be specifically designated for swimming by the use of regulatory buoys.
40.38(2) Reserved.

571—40.39(462A) Lost Island Lake, Palo Alto and Clay Counties.

- 40.39(1)** Areas may be specifically designated for swimming by the use of regulatory buoys.
40.39(2) Reserved.

571—40.40(462A) Ingham Lake, Emmet County.

- 40.40(1)** Areas may be specifically designated for swimming by the use of regulatory buoys.
40.40(2) Reserved.

571—40.41(462A) Storm Lake, Buena Vista County.

- 40.41(1)** Areas may be specifically designated for swimming by the use of regulatory buoys.
40.41(2) Reserved.

571—40.42(462A) Raccoon River Regional Park Lake, Polk County.

- 40.42(1)** All vessels shall be operated at a speed not greater than 5 miles per hour.
40.42(2) A 40-acre body of water located in the southeast corner, and separate from the main lake, shall be designated for nonmotorized and electric motors only. The city of West Des Moines will designate the area with regulatory buoys and signs.
40.42(3) Areas may be specifically designated for swimming by the use of regulatory buoys.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.43(462A) Zoning of the Mississippi River, Bellevue, Jackson County.

- 40.43(1)** All vessels shall be operated at a speed not greater than 5 miles per hour within the area designated by buoys or other approved uniform waterway markers beginning at the mouth of Mill Creek and extending upstream 900 feet, and extending 200 feet perpendicular from shore. The area shall be designated by a minimum of four approved buoys to be uniformly placed along the 900-foot length of the zone parallel to the shore.
40.43(2) The city of Bellevue will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.
[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.44(462A) Three Mile Lake, Union County—watercraft use. Motorboats of outboard or inboard-outdrive type shall be permitted on Three Mile Lake. The following rules shall govern vessel operation on Three Mile Lake in Union County.

- 40.44(1)** All vessels shall be operated at a speed not greater than 5 miles per hour when within 50 feet of another vessel which is not underway or is operating at a speed not greater than 5 miles per hour.

40.44(2) Zoned areas.

a. No vessel, except authorized emergency vessels, shall be permitted in areas specifically designated for swimming and wading which are plainly marked by use of regulatory buoys in accordance with Iowa Administrative Code 571—Chapter 41. The Union County conservation board shall designate and maintain a swimming area(s) by the use of regulatory buoys approved by the natural resource commission.

b. No motorboats, except authorized emergency vessels, shall be operated in marked bay areas at a speed greater than the limit designated by buoys or signs marking said bay. No motorboats, except authorized emergency vessels, shall be operated other than at a speed not greater than 5 miles per hour above a line of buoys placed across the lake at the point where County Road H33 intersects the lake. All buoys or signs shall be in accordance with 571—Chapter 41.

c. No motorboats, except authorized emergency vessels, shall be operated in restricted speed areas between the nearest shore and a line designated by regulatory buoys or signs at a speed greater than the limit designated on the buoys or signs marking the area. Such zoned areas shall be not less than 50 feet nor more than 400 feet from shore. Said buoys or signs shall be in accordance with 571—Chapter 41.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.45(462A) Zoning of the Cedar River.

40.45(1) *Nashua, Chickasaw County.* All vessels operated in a designated zone extending east 150 feet from the intersection of Wabash Street and Charles City Road and north 380 feet shall be operated at a speed not greater than 5 miles per hour. The city of Nashua shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

40.45(2) *Nashua, Chickasaw County.* All vessels operated in a designated zone extending north 131 feet from the intersection of Wabash Street and the north entrance to Cedar View Circle and east 80 feet and west 80 feet from this point along the shoreline and extending 110 feet north into the lake shall be operated at a speed not greater than 5 miles per hour. The city of Nashua shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

40.45(3) *Charles City, Floyd County.* All vessels operated in a designated zone extending 300 feet upstream from the upper dam shall be operated at a speed not greater than five miles per hour. The city of Charles City shall designate and maintain the five miles per hour speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.46(462A) Zoning of Carter Lake, Pottawattamie County.

40.46(1) All vessels operated in a designated zone known as Shoal Pointe Canal shall be operated at a speed not greater than 5 miles per hour.

40.46(2) The city of Carter Lake shall designate and maintain the 5-mile-per-hour speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.47(462A) Zoning of the Mississippi River, McGregor, Clayton County.

40.47(1) All vessels, except commercial barge traffic, shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 634 and 633.4 and designated by buoys or other approved uniform waterway markers.

40.47(2) The city of McGregor will designate the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.48(462A) Zoning of the Mississippi River, Marquette, Clayton County.

40.48(1) All vessels, except commercial barge traffic, shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 634.5 and 634.9 and designated by buoys or other approved uniform waterway markers.

40.48(2) The city of Marquette will designate and maintain the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.49(462A) Zoning of Green Island, Jackson County. All motorboats except authorized emergency vessels shall be operated at a speed no greater than 5 miles per hour year around on boat channels adjacent to the interior channel 4 levee at the Green Island State Wildlife area. Both channels begin at the Green Island county road parking lot and proceed north 7920 feet along each side of the channel 4 levee to an intersection with the Snag Slough complex.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.50(462A) Mooring of vessels on riparian property of the state of Iowa. Where the state of Iowa owns riparian property adjacent to sovereign land or water, mooring of vessels is prohibited between sunset and sunrise on those riparian or sovereign lands or waters where posted by either official buoys or official signs of the department of natural resources.

571—40.51(462A) Little River Lake, Decatur County. Motorboats of outboard or inboard-outdrive type shall be permitted on Little River Lake. Vessels operating within a designated area beginning at the dam and extending north approximately to the mouth of “Bait Shop Bay” shall be operated at a speed

no greater than 5 miles per hour. The Decatur County conservation board shall designate the speed zone with marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.52(462A) Zoning of the Mississippi River, Johnson Slough, Clayton County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 627 and 629.8, in a backwater known as Johnson Slough and designated by marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.53(462A) Zoning of the Mississippi River, Mud Lake, Dubuque County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area of river mile markers 587.6 to 589.3, in a backwater known as Mud Lake and designated by marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.54(462A) Nighttime speed limit, Dickinson County. No vessels, except authorized emergency vessels, shall be operated at speeds greater than 25 miles per hour at any time between one-half hour after sunset and sunrise on all lakes located in Dickinson County.

571—40.55(462A) Zoning of Clear Lake, Cerro Gordo County.

40.55(1) Areas may be specifically designated for swimming with the use of regulatory buoys.

40.55(2) Areas within close proximity of dredging operations may be designated as areas where the speed of vessels is restricted to not greater than 5 miles per hour.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.56(462A) Zoning of Mississippi River, Des Moines County, city of Burlington. All vessels shall be operated at a speed no greater than five miles per hour within the area designated by marker buoys or other approved uniform waterway markers beginning at the north city boat ramp and public dock and extending downstream to the south city boat ramp and public dock. The zoned area shall extend no farther than 150 feet from the shore and approximately 150 feet west of the west edge of the barge channel. The city of Burlington shall designate the five-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 7532B, IAB 1/28/09, effective 3/6/09]

571—40.57(462A) Zoning of Catfish Creek, Mines of Spain State Recreation Area, Dubuque County. All vessels shall be operated at a speed not greater than 5 miles per hour within the area beginning at the mouth of Catfish Creek and extending upstream to the confluence of Catfish Creek and Granger Creek and designated by uniform marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.58(462A) Zoning of Lake Cornelia, Wright County. All vessels shall be operated at a speed not greater than 5 miles per hour in the boat harbor and at the boat harbor entrance within the zoned area extending 300 feet from two points on shore and 100 feet in width, equidistant from either side of the harbor entrance. The Wright County conservation board shall designate the boat harbor entrance and the public swimming area with uniform marker buoys approved by the natural resource commission.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.59(462A) Zoning of lakes in Dickinson County. All vessels shall be operated at a speed not greater than 5 miles per hour within 300 feet of shore on all lakes in Dickinson County.

[ARC 8877B, IAB 6/30/10, effective 8/4/10]

571—40.60(462A) Zoning of the Mississippi River, Clayton, Clayton County.

40.60(1) All vessels, except commercial barge traffic, shall be operated at a speed no greater than 5 miles per hour within an area extending 150 feet from shore and beginning at a point 1,012 feet north

of Mississippi River Day Marker 624.7R and extending south to a point 1,012 feet south of the same marker (624.7R).

40.60(2) The city of Clayton shall designate and maintain the 5-mile-per-hour speed zone with buoys approved by the natural resource commission.

[ARC 1644C, IAB 10/1/14, effective 11/5/14]

571—40.61(321G,321I,462A) Beaver Creek safety zone. A safety zone is hereby established on Beaver Creek within the property boundaries of the Camp Dodge military reservation in Polk County.

40.61(1) Watercraft and vehicles shall be prohibited from entering the safety zone in order to prevent access to areas within Camp Dodge where a hazard to the public may exist. This prohibition shall not apply to watercraft or vehicles explicitly authorized to enter the safety zone by the Iowa national guard. The safety zone boundaries shall be indicated by signage including the wording “Warning, Restricted Area, No Entrance.” The Iowa national guard shall be responsible for the acquisition, placement, and maintenance of any signage.

40.61(2) The safety zone shall be recognized by the state of Iowa only where signage is posted as required. Any section of Beaver Creek that is not designated as a safety zone shall remain open to any otherwise lawful public access.

40.61(3) Signs establishing the safety zone boundaries may be moved within the present or future boundaries of Camp Dodge at the sole discretion of Iowa national guard personnel. The Iowa national guard shall notify the department of natural resources when the location of the safety zone boundary is changed.

This rule is intended to implement Iowa Code sections 321G.2, 321I.2, 462A.3, and 462A.26.

[ARC 5053C, IAB 6/17/20, effective 7/22/20]

These rules are intended to implement the provisions of Iowa Code sections 462A.17, 462A.26, and 462A.31.

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[◇] Two or more ARCs

CHAPTER 44
SPECIAL EVENTS AND FIREWORKS DISPLAYS

[Prior to 12/31/86, Conservation Commission[290] Ch 35]
[Prior to 6/1/11, see also 571—Chs 65 and 88 and subrule 61.7(16)]

571—44.1(321G,321I,461A,462A,481A) Scope. The purpose of this chapter is to provide rules on the issuance of permits for special events and fireworks displays held on public land, waters, and ice of the state.

[ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.2(321G,321I,461A,462A,481A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Accredited postsecondary institution or program” means an institution or program listed in the U.S. Department of Education’s database of accredited postsecondary institutions and programs.

“Administrative processing fee” means the fee collected for the processing of each special event application that is submitted.

“All-terrain vehicle” or *“ATV”* means a motorized flotation-tire vehicle with not less than three and not more than six low-pressure tires that is limited in engine displacement to less than 1,000 cubic centimeters and in total dry weight to less than 1,000 pounds and that has a seat or saddle designed to be straddled by the operator and handlebars for steering control.

“Bass fishing tournament” means an event with the purpose of fishing for black bass as defined in 2017 Iowa Acts, Senate File 257. For purposes of this chapter, “bass fishing tournament” is included in the definition of “special event” unless otherwise specified.

“Catfish fishing tournament” means an event with the purpose of fishing for catfish from boats that meets the definition of “fishing tournament.” For purposes of this chapter, “catfish fishing tournament” is included in the definition of “special event” unless otherwise specified.

“Centralized special events application system” means the web-based system used by applicants to submit applications for special events as permitted under this chapter. Approved applications shall be placed on a calendar of events web page, accessible from the department’s homepage, to inform the general public of scheduled events on public, or when applicable, private, land, water, and ice.

“Department” means the Iowa department of natural resources.

“Field and retriever meet or trial” means an event held on either private or public land where the skill of dogs in pointing, retrieving, trailing, or chasing any game bird, game animal, or fur-bearing animal is demonstrated. For purposes of this chapter, “field and retriever meet or trial” is included in the definition of “special event” unless otherwise specified.

“Fishing tournament” means any organized fishing event, except for department-sponsored fishing events held for educational purposes, involving any of the following: (1) six or more boats or 12 or more participants, except for waters of the Mississippi River, where the number of boats shall be 20 or more and the number of participants shall be 40 or more; (2) an entry fee is charged; or (3) prizes or other inducements are awarded. Additionally, a “virtual fishing tournament,” also known as a “catch-photo-release” tournament, is a fishing tournament where fish are not possessed (i.e., not placed in a live well) by the angler but instead are photographed and released upon catching. An “aggregated virtual fishing tournament” occurs when all participants are present on one body of water simultaneously. A “distributed virtual fishing tournament” occurs when participants are present on two or more bodies of water. Additionally, only five or fewer participants may be present on any one body of water simultaneously, and the tournament may occur over an extended time frame. For purposes of this chapter, “fishing tournament” is included in the definition of “special event” unless otherwise specified.

“Friends group” means an organization incorporated under Iowa Code chapter 504 or prior statutory authority as a not-for-profit group which has been formed solely for the purpose of promoting and enhancing a particular state park, recreation area, or the Iowa state park system, or any combination of the three.

“Off-road motorcycle” or *“ORM”* means a two-wheeled motor vehicle that has a seat or saddle designed to be straddled by the operator and handlebars for steering control and that is intended by the

manufacturer for use on natural terrain. “Off-road motorcycle” includes a motorcycle that was originally issued a certificate of title and registered for highway use under Iowa Code chapter 321, but which contains design features that enable operation over natural terrain.

“*Off-road utility vehicle*” or “*OHV*” means a motorized flotation-tire vehicle with not less than four and not more than eight low-pressure tires that is limited in engine displacement to less than 1,500 cubic centimeters and in total dry weight to not more than 1,800 pounds and that has a seat that is of bucket or bench design, not intended to be straddled by the operator, and a steering wheel or control levers for control. A motorized vehicle that was previously titled or is currently titled under Iowa Code chapter 321 shall not be registered or operated as an off-road utility vehicle.

“*Permit*” means a document issued by the department that enumerates all stipulations, requirements, and contingencies that the applicant must accept and adhere to throughout the duration of the approved special event.

“*Public land*” means land under the jurisdiction of the natural resource commission.

“*Public water*” means water and ice under the jurisdiction of the natural resource commission.

“*Sailing school*” means an organization that provides basic and advanced sailing instruction by U.S. Sailing-certified instructors and is affiliated with a yacht club, an accredited postsecondary institution or program, a private or public primary or secondary school, a scouting organization, or a religious institution.

“*Snowmobile*” means a motorized vehicle weighing less than 1,000 pounds which uses sled-type runners or skis, endless belt-type tread with a width of 48 inches or less, or any combination of runners, skis, or tread and which is designed for travel on snow or ice. “*Snowmobile*” does not include an all-terrain vehicle, as defined in Iowa Code section 321I.1, which has been altered or equipped with runners, skis, belt-type tracks, or treads.

“*Special event*” means either of the following occurring on public land, water, or ice:

1. An organized race, tournament, exhibition, demonstration, or other planned event in which an admission fee is charged, prizes are awarded, or competition occurs between participants;
2. A planned event that, due to its nature, potential or actual size, or length, would likely adversely impact the use of the area by the public.

“*Vessel*” means every description of watercraft, other than a seaplane, used or capable of being used as a means of transportation on water or ice.

[ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11; ARC 3443C, IAB 11/8/17, effective 12/13/17; ARC 5054C, IAB 6/17/20, effective 7/22/20]

DIVISION I SPECIAL EVENTS

571—44.3(321G,321I,461,462A,481A) Permit required. A permit is required in order to conduct a special event on any public land, water, or ice. A permit is also required for a field and retriever meet or trial held on private land.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.4(321G,321I,461A,462A,481A) Permit conditions. The department may impose permit conditions not specifically covered herein as deemed necessary to protect the resource or to ensure public safety. Such conditions shall be included in the permit issued by the department.

44.4(1) Use of concessionaire. If the state park or recreation area where a special event is being held has a concessionaire, the sale of food or drinks shall be governed pursuant to 571—Chapter 14. If a concessionaire chooses not to provide services during the special event, the event sponsor may bring in other concession operations as approved by the department.

44.4(2) Special permit conditions for fishing tournaments. In addition to permit conditions deemed necessary by rule 571—44.4(321G,321I,461A,462A,481A), the department may include some or all of the following permit conditions for fishing tournaments:

- a. Release of live fish.
- b. Fish measured to length and released from boat.

- c. Multiple weigh-ins when water temperatures exceed 70°F.
- d. Aerated live wells.
- e. Designated release areas.
- f. Designated release persons.

44.4(3) Catfish fishing tournaments. The daily catch limit for a catch and release catfish fishing tournament permitted under this chapter is five catfish per boat regardless of the number of tournament participants on the boat.

44.4(4) Bass fishing tournaments. In addition to permit conditions deemed necessary under the introductory paragraph of rule 571—44.4(321G,321I,461A,462A,481A) or under subrule 44.4(2), the permit conditions for bass fishing tournaments shall:

- a. State the minimum requirements for weigh-in, handling, and release of live bass by tournament participants.
- b. Allow for the measurement of bass to length and release from a vessel.
- c. Allow for the possession of up to five bass for weigh-in during the tournament.
- d. Allow for the possession of bass of any length, so long as the bass are kept alive and are released after weigh-in.

- e. Require the cleaning of vessels, before and after the tournament, in compliance with department guidelines to prevent the transportation of aquatic invasive species.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11; ARC 3443C, IAB 11/8/17, effective 12/13/17]

571—44.5(321G,321I,461A,462A,481A) Application procedures. The following procedures shall be used to apply for a special event permit:

44.5(1) Applications shall be made and submitted through the department's centralized special events application system.

44.5(2) Applications—when submitted.

- a. *Events for current year.* Applications may be submitted anytime during the calendar year in which the special event is to begin but no later than 30 days prior to the special event.
- b. *Events for the next year.* Applications for a special event that will start in the next calendar year shall not be submitted until September 1 of the current year.

44.5(3) The number of special events to be held at any area on the same day may be restricted if deemed necessary to avoid congestion within the area or to protect the resource.

44.5(4) One application form may be submitted for all events of the same type being held at the same location within a nine-day period and will be processed as a single application. A distributed virtual fishing tournament may extend beyond the nine-day period and need not be at a single location.

44.5(5) Submission of an application does not guarantee issuance of a permit.

44.5(6) Permits are nontransferable.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11; ARC 5054C, IAB 6/17/20, effective 7/22/20]

571—44.6(321G,321I,462A) Alternate dates for snowmobile, boating, all-terrain vehicle, off-highway vehicle, and off-road motorcycle special events. An applicant may submit and the department may approve both a primary date and an alternate date for snowmobile, boating, ATV, ORM, and OHV special events. However, if both a primary date and an alternate date are approved, the primary date shall be used unless circumstances beyond the control of the applicant prevent its use. If the alternate date must be used for the event, the applicant shall contact the program coordinator at least one week in advance of the date on which the event shall take place to obtain final approval to use the alternate date. The program coordinator shall document this approval in writing. Upon approval of an alternate date, the applicant shall notify the local conservation officer, and the program coordinator shall update the calendar of events.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.7(321G,321I,461A,462A,481A) Insurance coverage. The applicant shall secure liability insurance for the special event and shall name the department as an additional insured. Insurance information shall be available at the time the application is submitted. The applicant shall have a copy of the insurance policy available at the event location to present to department personnel if requested. These requirements shall not apply to events sponsored by a friends group. The department reserves the right to waive these requirements on a case-by-case basis.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.8(321G,321I,461A,462A,481A) Fees and exceptions. The administrative fee for processing each special event application is \$25. In the case of field and retriever meets and trials, the fee for processing each special event application is \$2. The fees are nonrefundable.

The department shall waive the administrative fee for processing special event applications for sailing schools; accredited postsecondary institutions and programs; private and public primary and secondary schools; all department-approved watercraft education courses, ATV education courses, and snowmobile education courses; fishing clinics; friends groups; department-sponsored youth fishing days; and distributed virtual fishing tournaments.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11; ARC 5054C, IAB 6/17/20, effective 7/22/20]

571—44.9(321G,461A) Structures placed on ice during a special event. The following requirements apply to the placement, construction, or erection of structures on ice during a special event:

44.9(1) Vendor information provided on application. The applicant shall identify the names and addresses of any vendors who will be on site during the special event.

44.9(2) Owner information. The full name, street address, and city of the structure's owner shall be displayed legibly on all sides of the structure, in block letters at least four inches in height, and in a color contrasting to the background.

44.9(3) Accessibility. Structures shall not be locked when in use.

44.9(4) Reflectors. Reflectors shall be attached to all sides of the structure in such a manner to enable them to reflect light at all times from sunrise to sunset.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.10(462A) Boating special events—registration exemptions.

44.10(1) A vessel entered in a boating special event shall not be required to be registered pursuant to Iowa Code sections 462A.4 and 462A.5 but shall be labeled with an identifying number or letter that is at least four inches high and is in a color contrasting to the vessel. The identifying number or letter shall be located in a prominent spot on the exterior of the vessel, other than on the bow.

44.10(2) The sponsor of the boating special event shall maintain a list containing:

a. The names and addresses of all persons participating in the event.

b. A description of each vessel in the event. The description of each vessel shall include the identifying number or letter of the vessel as required by 44.10(1).

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.11(462A) Mississippi River or Missouri River. Upon notification and proof that a United States Coast Guard (U.S.C.G.) permit has been secured, the department shall not require a special event application for fireworks displays or boating special events on the Mississippi River or the Missouri River. The regional U.S.C.G. office issuing permits for Mississippi River and Missouri River events is located in St. Louis, Missouri. This rule does not apply to fishing tournaments.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.12(321G,321I,461A,462A,481A) Other requirements and permits. The applicant for a permit is responsible for ensuring full compliance with the requirements of Iowa Code chapters 321G,

321I, 461A, 462A, and 481A, and any other Iowa Code chapters and rules promulgated under those chapters that may be applicable to special events. The applicant shall also acquire and comply with all applicable state and local permits issued by other state and local agencies necessary to hold the special event.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.13(321G,321I,461A,462A,481A) Authority to cancel or stop a special event. If a peace officer or any department employee determines that a permit is being violated or that safety concerns warrant canceling or stopping the special event, the peace officer or department employee has the authority to cancel or stop the special event.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.14(321G,321I,461A,462A,481A) Nonexclusive use of area. Issuance of a permit does not grant the applicant exclusive use of the public land, water, or ice that is the subject of the permit unless the permit explicitly provides otherwise.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

DIVISION II FIREWORKS DISPLAYS

571—44.15(461A) Entities eligible for permits. Permits for fireworks displays shall be issued only to qualified entities, such as political subdivisions of the state of Iowa, and to community or civic organizations, such as chambers of commerce, junior chambers of commerce (Jaycees), rotary clubs, and Elks Lodges and similar fraternal benefit associations or societies. Permits shall not be issued to individuals. Permits are not transferable to another entity and do not relieve the sponsoring entity from obtaining any other permits required by the state or its political subdivisions.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.16(461A) Permit conditions. The department may impose permit conditions not specifically required in these rules for any fireworks display special event as deemed necessary to protect the resource or ensure public safety. Conditions shall be included in the permit that the applicant or sponsoring organization receives if the event is approved.

[ARC 8815B, IAB 6/2/10, effective 7/7/10 (See Delay note at end of chapter); ARC 9114B, IAB 10/6/10, effective 9/10/10; ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.17(461A) Application procedures. The following procedures shall be used to apply for a permit:

44.17(1) Applications shall be made and submitted through the department's centralized special events application system.

44.17(2) Applications—when submitted.

a. Events for current year. Applications may be submitted anytime during the calendar year in which the fireworks display is to begin but no later than 30 days prior to the display.

b. Events for the next year. Applications for a fireworks display that will start in the next calendar year shall not be submitted until September 1 of the current year.

44.17(3) The number of fireworks displays or other special events at any one public land, water or ice location during a given day may be restricted if deemed necessary to avoid congestion with the public or competing events and to protect the resource.

44.17(4) The applicant shall certify in the application that the fireworks display shall be conducted by a competent operator. The location of the display shall be determined by the department representative in charge of the area.

44.17(5) Submission of an application does not guarantee issuance of a permit by the department.

[ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.18(461A) Fireworks display procedures.

44.18(1) The sponsoring entity shall take adequate safety precautions to ensure that persons not actively involved in conducting the display remain a safe distance from the firing area and any areas containing set pieces.

44.18(2) The department representative in charge of the area in which the display is conducted or any state peace officer may halt any display when the character, location, weather, or firing of the display makes it hazardous to property or dangerous to any person.

44.18(3) Any fireworks that remain unfired after the display is concluded shall be immediately disposed of by the operator or the sponsoring entity in a manner that is safe for the particular type of fireworks.

44.18(4) The sponsoring entity shall make arrangements for firefighting equipment and emergency medical services to be on the scene at all times during the firing of the display.

44.18(5) The sponsoring entity is totally responsible for cleanup of the fireworks display site at the conclusion of the display.

[ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.19(461A) Fees. A nonrefundable administrative fee of \$25 shall be charged for processing each fireworks display application.

[ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.20(461A) Insurance. The sponsoring entity for a fireworks display shall provide proof of liability insurance naming the applicant and the department as an additional insured in the sum of not less than \$1 million. The department may, at its discretion, require a greater amount. Insurance information shall be available at the time the application is submitted.

[ARC 9539B, IAB 6/1/11, effective 7/6/11]

571—44.21(461A) Concessions. If the state park or recreation area has a concessionaire on site, sales of food and other items during the display shall be governed pursuant to 571—Chapter 14. If a concessionaire chooses not to provide services during the event, the sponsoring entity may then bring in other concession operations as approved by the department.

[ARC 9539B, IAB 6/1/11, effective 7/6/11]

These rules are intended to implement Iowa Code sections 321G.16, 321I.17, 461A.3, 461A.4, 461A.42, 461A.47, 461A.57, 462A.16, 481A.22, and 481A.38.

[Filed 11/2/84, Notice 9/26/84—published 11/21/84, effective 1/1/85]

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[Filed ARC 8815B (Notice ARC 8462B, IAB 1/13/10), IAB 6/2/10, effective 7/7/10]¹

[Editorial change: IAC Supplement 6/30/10]

[Filed Emergency ARC 9114B, IAB 10/6/10, effective 9/10/10]

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[Filed ARC 5054C (Notice ARC 4924C, IAB 2/12/20), IAB 6/17/20, effective 7/22/20]

¹ July 7, 2010, effective date of ARC 8815B delayed for 70 days by the Administrative Rules Review Committee at its meeting held June 8, 2010.

CHAPTER 54
RESTRICTIONS ON INTRODUCTION AND REMOVAL OF PLANT LIFE
[Prior to 12/31/86, Conservation Commission[290] Ch 47]

571—54.1(461A) Mushrooms and asparagus. Lands under the jurisdiction of the commission shall be open for the harvesting of mushrooms and asparagus during the hours the areas are open to the public. [ARC 8594B, IAB 3/10/10, effective 4/14/10]

571—54.2(461A) Fruit. Lands under the jurisdiction of the commission shall be open for the harvesting of all varieties of nuts, fruits, and berries unless signs are posted prohibiting such activity. Nut, fruit, and berry gathering shall be permitted only during the hours the areas are open to the public and shall not be permitted in state preserves unless otherwise allowed by the preserves management plan. [ARC 8594B, IAB 3/10/10, effective 4/14/10]

571—54.3(461A) American ginseng. The harvesting of American ginseng (*Panax quinquefolius*) is subject to regulation by 571—Chapter 78.

This rule is intended to implement Iowa Code sections 456A.24(11) and 461A.41. [ARC 8594B, IAB 3/10/10, effective 4/14/10]

571—54.4(461A) Trees. The commercial harvest of trees from lands under the jurisdiction of the commission shall be done in accordance with 561—8.5(17A,456A,461A) and 561—8.6(455B), according to the department's Forest Ecosystem Management Guide, approved by the natural resource commission on December 8, 1994, and hereby adopted by reference.

This rule is intended to implement Iowa Code sections 461A.35 and 461A.41.

571—54.5(461A) Aquatic plants. This rule applies to the introduction and removal of plants in public waters as those waters are defined by rule 571—13.2(455A,461A,462A). For purposes of this rule, aquatic plants are those listed in subrule 54.5(6) and include vegetation that exists at or below the ordinary high water line of a waterway.

54.5(1) Permits.

a. The department may issue permits for the introduction and removal of aquatic plants in public waters. To be considered for a permit under this rule, applicants shall use the department's application form for sovereign lands construction permits, as described in rule 571—13.9(455A,461A,462A), and shall complete all relevant information on that application form. Applicants shall also provide any additional information as may be necessary, as described in rule 571—13.10(455A,461A). The term of the permit shall be stated in the permit. Permits are nontransferable and shall be subject to reevaluation upon expiration. Permits may be issued for between one and five years.

b. Cities and counties in Iowa may use chemicals, including pesticides and herbicides, to remove aquatic vegetation from water intake structures. However, such cities and counties shall be required to obtain a permit under this rule, and 567—Chapter 66 as may be required, for such activities.

c. Cities and counties in Iowa may use chemicals, including pesticides and herbicides, to remove aquatic vegetation for certain recreation and navigation purposes, including boating, fishing, and swimming. However, such cities and counties shall be required to obtain a permit under this rule, and 567—Chapter 66 as may be required, for such activities. Additionally, all such use of chemicals shall be conducted by a certified aquatic applicator and shall be subject to the terms of a vegetation management plan approved by the director. Issuance of such permits and approval of a vegetation management plan shall be at the sole discretion of the department.

54.5(2) Evaluation. The department shall evaluate all permits sought under this rule in accordance with the evaluation criteria enumerated in rule 571—13.6(455A,461A,462A). In addition, the department shall consider the following criteria:

a. For aquatic plant introduction:

(1) Unless otherwise approved by the department, all introduced plants shall be included in the list provided in subrule 54.5(6);

(2) Introduced plants shall not include cultivars;

(3) Plants shall be introduced for the purposes of preventing shoreline erosion, stabilizing bottom sediment, providing fish or wildlife habitat, or removing nutrients from the water;

(4) Plants shall be thoroughly rinsed away from the water into which they are being introduced prior to being transported to the site if the plants have not been cultivated on site in a manner to prevent any foreign nonplant or seed material from entering the water prior to introduction; and

(5) Plants shall be obtained from a seed source that is within 50 miles of the introduction area and from stocks of only cultivated material (i.e., material that has not been taken from natural areas) or from a source that is approved by the department. Approval for a seed source may be sought from the department by contacting the area fisheries management biologist.

b. For aquatic plant removal:

(1) The plants shall be removed by hand-cutting, hand-pulling, hand-raking or mechanical cutting only;

(2) The plants shall be removed to establish a designated travel lane from a boat dock that has been permitted in accordance with 571—Chapter 16. Such travel lane shall not exceed a 15-foot width, and the placement of such lane shall be subject to the review and approval of the department. A travel lane allowed under this rule may be in the same location during the term of the permit, may be sited by the department to accommodate vegetation, and may not necessarily be the most direct path from the dock to the open water area; and

(3) All plant material removed under the permit must be left in place or collected and composted on the land owned, leased or otherwise subject to use by the applicant that is adjacent to the removal area.

Unless otherwise provided by this rule, in no event may a person be allowed to apply chemicals including, without limitation, pesticides or herbicides to remove aquatic plants from public waters. For nonpublic waters that meet certain designations in 567—Chapter 66, a person may be required to seek a permit under the rules established herein to use pesticides.

54.5(3) Inspection requirements. For the purpose of inspecting for compliance with permit conditions, the department shall have the right to enter the property attached to the public water at or near the place of introduction or removal. This inspection shall include, without limitation, identification of introduced species; a determination as to whether the travel lane is being maintained in accordance with the permit conditions; and whether plant material, if removed, is left on site.

54.5(4) Violations. Persons in violation of this rule are guilty of a simple misdemeanor as described by Iowa Code section 461A.57.

54.5(5) Exceptions.

a. A dock permittee whose dock meets rule 571—16.4(461A,462A), 571—16.6(461A,462A), or 571—16.7(461A,462A) may remove aquatic vegetation without a permit if the aquatic vegetation:

- (1) Creates a hazardous or detrimental condition in the boating area around the dock, or
- (2) Covers a minimum of 75 percent of the boating area around the dock.

b. A dock permittee meeting one of the exceptions in paragraph 54.5(5)“a” must verify at inspection that the dock meets the criteria for a Class I, Class II or Class III dock permit and is limited to the following:

- (1) Removal of vegetation in a 20-foot radius around the dock;
- (2) Removal of a hazardous or detrimental condition when it interferes with safe boating passage and is located within the boating area around the dock;
- (3) Creation of a 15-foot-wide boating pathway utilizing a direct route from the dock to open water;
- (4) Adherence to the requirement to leave the vegetation in place or collect and compost it on land that is owned, leased or otherwise subject to use by the dock permittee and is adjacent to the removal area;

(5) Removal of the vegetation by hand-cutting, hand-pulling, hand-raking or mechanical cutting devices, excluding automated plant control devices that disturb the bottom substrate.

54.5(6) Appropriate plants. The department is committed to maintaining the natural integrity of public waters in the state and strengthening native populations of vegetation and wildlife in those waters.

To that end, the following table comprises the plants that may be permitted to be introduced into public waters:

Scientific Name	Common Name
<i>Acorus americanus</i>	Sweet Flag
<i>Alisma plantago-aquatica</i>	Water Plantain
<i>Asclepias incarnata</i>	Marsh Milkweed
<i>Bidens cernua</i>	Nodding Beggars Ticks
<i>Bidens coronata</i>	Tickseed Sunflower
<i>Brasenia schreberi</i>	Water Shield
<i>Calamagrostis canadensis</i>	Blue Joint Grass
<i>Caltha palustris</i>	Marsh Marigold
<i>Carex atherodes</i>	Wheat Sedge
<i>Carex comosa</i>	Longhair Sedge
<i>Carex cristatella</i>	Crested Sedge
<i>Carex hystericina</i>	Bottlebrush Sedge
<i>Carex lacustris</i>	Hairy Sedge
<i>Carex normalis</i>	Greater Straw Sedge
<i>Carex pellita</i>	Wooly Sedge
<i>Carex prairea</i>	Prairie Sedge
<i>Carex scoparia</i>	Broom Sedge
<i>Carex stipata</i>	Awlfruit Sedge
<i>Carex stricta</i>	Upright Sedge
<i>Carex tribuloides</i>	Blunt Broom Sedge
<i>Carex vulpinoidea</i>	Fox Sedge
<i>Ceratophyllum demersum</i>	Coontail
<i>Eleocharis acicularis</i>	Needle Spikerush
<i>Eleocharis obtuse</i>	Blunt Spikerush
<i>Elodea canadensis</i>	Canada Waterweed
<i>Eupatorium perfoliatum</i>	Boneset
<i>Glyceria striata</i>	Fowl Manna Grass
<i>Iris versicolor</i>	Blue Flag Iris
<i>Juncus dudleyi</i>	Dudley's Rush
<i>Juncus torreyi</i>	Torrey's Rush
<i>Leersia oryzoides</i>	Rice Cutgrass
<i>Lobelia siphilitica</i>	Great Lobelia
<i>Lysimachia ciliate</i>	Fringed Loosestrife
<i>Lythrum alatum</i>	Winged Loosestrife
<i>Muhlenbergia mexicana</i>	Leafy Satin Grass
<i>Muhlenbergia racemosa</i>	Marsh Muhly
<i>Nymphaea tuberosa</i>	White Water Lily
<i>Poa palustris</i>	Fowl Bluegrass
<i>Polygonum amphibium</i>	Water Smartweed
<i>Pontederia cordata</i>	Pickerelweed
<i>Potamogeton nodosus</i>	Longleaf Pondweed
<i>Ranunculus secleratus</i>	Cursed Crowfoot

<i>Sagittaria latifolia</i>	Broadleaf Arrowhead
<i>Schoenoplectus acutus</i>	Hardstem Bulrush
<i>Schoenoplectus fluviatilis</i>	River Bulrush
<i>Schoenoplectus tabernaemontani</i>	Soft-Stem Bulrush
<i>Scirpus atrovirens</i>	Green Bulrush
<i>Sparganium eurycarpum</i>	Giant Burreed
<i>Spartina pectinata</i>	Prairie Cord Grass
<i>Stuckenia pectinatus</i>	Sago Pondweed
<i>Typha latifolia</i>	Broadleaf Cattail

In addition, an applicant may propose, as part of the application, species that do not appear on this list, which the department will consider. The department's consideration of species not on this list will be based on the commitment described above as well as the potential impact of the proposed species to the public water and ecosystem.

[ARC 8594B, IAB 3/10/10, effective 4/14/10; ARC 1703C, IAB 10/29/14, effective 12/3/14; ARC 5055C, IAB 6/17/20, effective 7/22/20]

These rules are intended to implement Iowa Code chapter 461A.

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CHAPTER 81
FISHING REGULATIONS
[Prior to 12/31/86, Conservation Commission[290] Ch 108]

571—81.1(481A) Seasons, territories, daily bag limits, possession limits, and length limits.

KIND OF FISH	INLAND WATERS OF THE STATE			BOUNDARY RIVERS	
	OPEN SEASON	DAILY BAG LIMIT	POSSESSION LIMIT	MINIMUM LENGTH LIMITS	MISSISSIPPI RIVER MISSOURI RIVER BIG SIOUX RIVER
Rock Sturgeon	Closed	0	0	0	Same as inland waters
Shovelnose Sturgeon	Continuous	None	None	None	Same as inland waters except no harvest allowed in the Big Sioux River and aggregate daily bag limit 10, aggregate possession limit 20, in the Missouri River
Paddlefish*	Continuous	2	4	None	Mississippi River—Same as inland waters except for an open season and length limit; see below* Missouri and Big Sioux Rivers—Special regulations; see below*
Yellow Perch	Continuous	25	50	None	Same as inland waters except no bag or possession limit in the Missouri River
Trout	Continuous	5	10	None*	Same as inland waters
Catfish*	Continuous	8 Lakes 15 Streams	30	None	Same as inland waters except no bag or possession limit in the Mississippi River
Black Bass (Largemouth Bass) (Smallmouth Bass) (Spotted Bass)	Continuous	3 In Aggregate	6	See below*	Continuous open season; aggregate daily bag limit 5, aggregate possession limit 10 See below*
Combined Walleye, Sauger and Saugeye	Continuous*	5*	10*	None*	Continuous open season; aggregate daily bag limit 6, aggregate possession limit 12; except aggregate daily bag limit 4, aggregate possession limit 8, in the Big Sioux and Missouri Rivers See below*
Northern Pike	Continuous*	3	6	None	Continuous open season; daily bag limit 5, possession limit 10; except daily bag limit 6, possession limit 12, in the Big Sioux River

KIND OF FISH	INLAND WATERS OF THE STATE				BOUNDARY RIVERS
	OPEN SEASON	DAILY BAG LIMIT	POSSESSION LIMIT	MINIMUM LENGTH LIMITS	MISSISSIPPI RIVER MISSOURI RIVER BIG SIOUX RIVER
Muskellunge or Hybrid Muskellunge	Continuous*	1	1	40"	Same as inland waters
Crappie	Continuous	25*	None	None	Same as inland waters except 50 in possession
Bluegill	Continuous	25*	None	None	Same as inland waters except in aggregate with pumpkinseed on the Mississippi River
All other fish species*	Continuous	None	None	None	See below*
Frogs (except Bullfrogs)	Continuous	48	96	None	Same as inland waters
Bullfrogs (<i>Rana Catesbeiana</i>)	Continuous	12	12	None	Same as inland waters

*Also see 571—81.2(481A), Exceptions.

[ARC 8195B, IAB 10/7/09, effective 11/11/09; ARC 1702C, IAB 10/29/14, effective 12/3/14]

571—81.2(481A) Exceptions to seasons and limits, set in 81.1(481A).

81.2(1) Exception closed season. In Lakes West Okoboji and East Okoboji and Spirit Lake, there shall be a closed season on walleye beginning February 15 each year. The annual opening for walleye in these three lakes shall be the first Saturday in May. In these three lakes there shall be an open season on muskellunge and tiger muskie from May 21 through November 30.

81.2(2) Black bass. The department may post season, bag or possession limits, length limits, and catch and release regulations specific to a body of water at that body of water. For bodies of water without posted regulations, the following regulations apply to black bass:

- a. A 15-inch minimum length limit shall apply on black bass in all public lakes.
- b. A 12-inch minimum length limit shall apply on black bass in all interior streams, river impoundments, and the Missouri River including chutes and backwaters of the Missouri River where intermittent or constant flow from the river occurs.
- c. A 14-inch minimum length limit shall apply to the Mississippi River including chutes and backwaters where intermittent or constant flow from the river occurs.

81.2(3) Walleye.

a. *West Okoboji, East Okoboji, Spirit, Upper Gar, Minnewashta, and Lower Gar Lakes in Dickinson County, Storm Lake in Buena Vista County, Clear Lake in Cerro Gordo County, and Big Creek Lake in Polk County.* The daily bag limit shall be three, with a possession limit of six.

b. *Length limits.* Length limits shall apply on walleye in public waters that have length limits posted or published.

81.2(4) Paddlefish snagging is permitted in waters of the state designated in rule 571—81.1(481A), except as follows:

a. There shall be no open season above the Interstate 29 bridge in the Big Sioux River, nor in any tributary of this stream within 200 yards immediately upstream of a tributary confluence.

b. Snagging for paddlefish on the Missouri and Big Sioux Rivers is limited to Iowa waters only, beginning in the Big Sioux River below the Interstate 29 bridge to the Big Sioux River's confluence with the Missouri River and in the Missouri River, including all backwaters and sloughs and any tributary of the Missouri River at its confluence and extending below its Interstate 29 bridge, beginning at the Big Sioux River confluence and extending to the Hamburg Landing boat ramp.

- (1) There shall be an open season from February 1 through April 30.
- (2) Snagging hours are from sunrise to sunset.

(3) The bag limit is one paddlefish per paddlefish fishing license.

(4) The paddlefish fishing license quota is 950 for resident anglers and 50 for nonresident anglers. Licenses shall be issued on a first-come, first-served basis. A person may purchase one paddlefish fishing license from December 15 through December 31 and either a first or second license between January 1 and January 7. No duplicate license or transportation tag shall be issued after the start of the season.

(5) Each angler fishing for paddlefish and any species listed in subrule 81.2(11) on the Missouri and Big Sioux Rivers shall have a valid paddlefish fishing license and unused tag. All snagged fish except for a species listed in subrule 81.2(11) or a legal paddlefish taken into possession shall immediately be released alive.

(6) Immediately upon an angler's taking into possession a legal paddlefish, a valid current year transportation tag issued with the license shall be visibly attached to the fish's lower jaw. The tag must be attached in such a manner that it cannot be removed without mutilating or destroying the tag. An angler shall not possess a paddlefish fishing license or transportation tag issued to another angler or tag a paddlefish with a transportation tag issued to another angler. The transportation tag shall be attached before the carcass can be moved in any manner from the place of harvest. The transportation tag shall remain affixed to the paddlefish until the paddlefish is processed for consumption. The paddlefish shall remain intact except for the snout in front of the eye until the fish reaches the final processing place. For the purposes of this subrule, the "final processing place" is defined as the angler's residence or the location where consumption occurs. The transportation tag shall be proof of possession of the carcass by the above-mentioned licensee. During the closed season, the possession of paddlefish on the Missouri and Big Sioux Rivers is prohibited unless the paddlefish are legally taken in Nebraska or South Dakota.

(7) No hooks larger than 5/0 treble or measuring more than 1¼ inches in length when two of the hook points are placed on a ruler are permitted when snagging.

(8) A gaffe hook or other penetrating device may not be used as an aid in the landing of a snagged fish.

c. Snagging for paddlefish on the Mississippi River is restricted to the area within 500 yards below the navigation dams and their spillways. No hooks larger than 5/0 treble or measuring more than 1¼ inches in length when two of the hook points are placed on a ruler are permitted when snagging. The open season on the Mississippi River is the period from March 1 through April 15.

d. Except during the Missouri and Big Sioux Rivers open paddlefish fishing season, snagging for paddlefish is not permitted at any time in those areas where snagging is prohibited as a method of take as listed in subrule 81.2(11).

e. On the Mississippi River, a 33-inch maximum length limit shall apply; any paddlefish measuring 33 inches or more when measured from the front of the eye to the natural unaltered fork of the tail must immediately be released alive. On the Missouri and Big Sioux Rivers and on each Missouri River tributary from its confluence and extending to below its Interstate 29 bridge, a 35-inch to 45-inch protected-slot limit shall apply; a paddlefish measuring 35 inches to 45 inches when measured from the front of the eye to the natural unaltered fork of the tail shall immediately be released alive. To measure a paddlefish, the angler shall use a flexible tape and measure along and over the center line contour of the fish while it is lying flat.

81.2(5) Trout regulations. The department may post season, bag or possession limits, length limits, catch and release regulations, and tackle restrictions specific to a body of water at that body of water. On bodies of water posted as artificial lure only, "artificial lure" means lures that do not contain or have applied to them any natural or synthetic substances designed to attract fish by the sense of taste or smell. For bodies of water without posted regulations, the following regulations apply to trout:

a. Open season is continuous.

b. A five-fish daily bag limit and ten-fish possession limit shall apply to any combination of brown trout, brook trout, rainbow trout, and their hybrids.

c. A trout fee is required to fish for and possess trout.

81.2(6) Exception border lakes. In Little Spirit Lake, Dickinson County; Iowa and Tuttle (Okamanpedan) Lakes, Emmet County; Burt (Swag) Lake, Kossuth County; and Iowa Lake, Osceola

County, the following species have a continuous open season and daily bag and possession limits as set forth below:

- a. Walleye—daily bag and possession limit 3;
- b. Northern pike—daily bag and possession limit 3;
- c. Largemouth and smallmouth bass—daily bag and possession limit 3;
- d. Channel catfish—daily bag and possession limit 8;
- e. Yellow perch—daily bag and possession limit 25;
- f. Crappie species—combined daily bag and possession limit 25;
- g. Sunfish (bluegill, pumpkinseed, green sunfish, orangespotted sunfish, longear sunfish, warmouth, and hybrids)—combined daily bag and possession limit 25;
- h. White bass, yellow bass, bullhead, common carp, bowfin, suckers, sheepshead, buffalo, gar and quillback—no daily bag or possession limit;
- i. Muskellunge—daily bag and possession limit one. Open season shall be May 21 through November 30. A 40-inch minimum length limit shall apply on all border lakes;
- j. Spears and bow and arrow may be used to take carp, buffalo, bowfin, gar, sheepshead, and quillback carpsucker with a continuous open season;
- k. All species not listed above are subject to the inland regulations of the state and have a continuous open season.

81.2(7) DeSoto Bend Lake. All fishers shall conform with federal refuge regulations as posted under the authority of Section 33.19 of Title 50 CFR. The text of the rules will be contained on the signs as posted.

81.2(8) General restriction. Anglers must comply with the most restrictive set of regulations applicable to the water on which they are fishing. Where length limits apply, fish less than the legal length must be immediately released into the water from which they were caught.

81.2(9) Catfish. For the purpose of this rule, stream catfish bag and possession limits apply at the federal flood control impoundments of Rathbun Lake, Red Rock Lake, Saylorville Lake, and Coralville Lake.

81.2(10) Identification of catch. No person shall transport or possess on any waters of the state any fish unless (a) the species of any such fish can be readily identified and a portion of the skin (at least 1 square inch) including scales is left on all fish or fillets and (b) the length of fish can be determined when length limits apply. “On any waters of the state” includes from the bank or shoreline in addition to wading and by boat.

81.2(11) Method of take. Artificial light may be used in the taking of any fish. The following species of fish may be taken by snagging, spearing, and bow and arrow: common carp, bighead carp, grass carp, silver carp, black carp, bigmouth buffalo, smallmouth buffalo, black buffalo, quillback carpsucker, highfin carpsucker, river carpsucker, spotted sucker, white sucker, shorthead redhorse, golden redhorse, silver redhorse, sheepshead, shortnose gar, longnose gar, dogfish, gizzard shad, and goldfish. All other species of fish not hooked in the mouth, except paddlefish legally taken by snagging, must be returned to the water immediately with as little injury as possible. A fish is foul hooked when caught by a hook in an area other than in the fish’s mouth. Snagging is defined as the practice of jerking any type of hook or lure, baited or unbaited, through the water with the intention of foul hooking fish. No hook larger than a 5/0 treble hook or measuring more than 1¼ inches in length when two of the hook points are placed on a ruler are permitted when snagging. Exceptions to snagging as a method of take are as follows:

- a. No snagging is permitted in the following areas:
 - (1) Des Moines River from directly below Saylorville Dam to the Southeast 14th Street bridge in Des Moines.
 - (2) Cedar River in Cedar Rapids from directly below the 5 in 1 Dam under Interstate 380 to the 1st Avenue bridge.
 - (3) Cedar River in Cedar Rapids from directly below the “C” Street Roller Dam to 300 yards downstream.
 - (4) Iowa River from directly below the Coralville Dam to 300 yards downstream.
 - (5) Chariton River from directly below Lake Rathbun Dam to 300 yards downstream.

- (6) Spillway area from directly below the Spirit Lake outlet to the confluence at East Okoboji Lake.
- (7) Northeast bank of the Des Moines River from directly below the Ottumwa Dam, including the catwalk, to the Jefferson Street Bridge. Snagging from the South Market Street Bridge is also prohibited.
- (8) Missouri River, any Missouri River tributary beginning at its confluence and extending below its Interstate 29 bridge and the Big Sioux River from the Interstate 29 bridge to the confluence with the Missouri River, with the exception of snagging paddlefish or any of the species listed in subrule 81.2(11) during the paddlefish open season.
- (9) Des Moines River from directly below the Hydroelectric Dam (Big Dam) to the Hawkeye Avenue Bridge in Fort Dodge.
- (10) Des Moines River from directly below the Little Dam to the Union Pacific Railroad Bridge in Fort Dodge.
- (11) Skunk River from directly below Oakland Mills Dam to the downstream end of the 253rd Street boat ramp.

b. No snagging, bow and arrow fishing, or spearing of fish is permitted in the following areas:

- (1) Clear Lake and Ventura Marsh from the Ventura Grade, Jetties and Bridge.
- (2) Lost Island Lake Inlet within 300 feet of the concrete culvert and metal fish barrier.
- (3) Lost Island Lake Outlet within 300 feet of the outlet structure and metal fish barrier.
- (4) Barringer Slough Outlet within 300 feet of the outlet and metal fish barrier.
- (5) The outlet area of Lower Gar Lake beginning at 230th Avenue and extending downstream to the signed Iowa Great Lakes Sanitary District property line.

81.2(12) Panfish. The daily bag limit for crappie and bluegill applies only to public waters of the state. In all waters of the Mississippi River, the daily bag and possession limit applied individually to crappie, yellow perch and rock bass shall be 25 and 50, respectively. In all waters of the Mississippi River, the daily bag and possession limit applied in the aggregate for bluegill and pumpkinseed and for white bass and yellow bass shall be 25 and 50, respectively.

81.2(13) Culling. It is prohibited to sort, cull, high-grade, or replace any fish already in possession. Participants in permitted black bass fishing tournaments are exempted, as are participants in catch and release catfish fishing tournaments if the participants are fishing from a boat with a functioning aerated or water-circulated live well. Any fish taken into possession by holding in a live well, on a stringer or in other fish-holding devices is part of the daily bag limit. Once the daily bag limit of a particular species is reached, fishing for that species is permitted as long as all fish of that species caught are immediately released.

[ARC 8195B, IAB 10/7/09, effective 11/11/09; ARC 9052B, IAB 9/8/10, effective 10/13/10; ARC 1702C, IAB 10/29/14, effective 12/3/14; ARC 3443C, IAB 11/8/17, effective 12/13/17; ARC 5056C, IAB 6/17/20, effective 7/22/20]

571—81.3(481A) Trotlines and throw lines.

81.3(1) *Where permitted.* It shall be lawful to use trotlines or throw lines in all rivers and streams of the state, except in Mitchell, Howard, Winneshiek, Allamakee, Fayette, Clayton, Delaware, Dubuque, and Jackson Counties. Trotlines or throw lines may be used in the above nine counties in the following stream segments: Mississippi River; Maquoketa River, mouth to Backbone State Park Dam; North Fork Maquoketa River, mouth to Jones-Dubuque County line; Turkey River, mouth to the Elkader Dam; and Upper Iowa River, mouth to the first dam upstream in Winneshiek County.

81.3(2) *Removal of lines.* All trotlines and parts thereof shall be removed from the shore when they are not being actively fished. A trotline shall be considered actively fished if at least once daily the trotline is left with at least one baited hook in the water.

[ARC 1702C, IAB 10/29/14, effective 12/3/14]

These rules are intended to implement Iowa Code sections 481A.38, 481A.39, 481A.67 and 481A.76.

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CHAPTER 91
WATERFOWL AND COOT HUNTING SEASONS
[Prior to 12/31/86, Conservation Commission[290] Ch 107]

571—91.1(481A) Duck hunting.

91.1(1) Zone boundaries. The following zone boundaries apply in the time frames noted:

a. For the 2020-2021 season, the north duck hunting zone is that part of Iowa north of a line beginning on the South Dakota-Iowa border at Interstate 29, southeast along Interstate 29 to State Highway 175, east to State Highway 37, southeast to State Highway 183, northeast to State Highway 141, east to U.S. Highway 30, and along U.S. Highway 30 to the Iowa-Illinois border. The Missouri River duck hunting zone is that part of Iowa west of Interstate 29 and south to the Iowa-Missouri border. The south duck hunting zone is the remainder of the state.

b. For the fall 2021 through spring 2026 seasons, the north duck hunting zone is that part of Iowa north of a line beginning on the South Dakota-Iowa border at Interstate 29, southeast along Interstate 29 to State Highway 20 to the Iowa-Illinois border. The south duck hunting zone is that part of Iowa west of Interstate 29 and south of State Highway 92 east to the Iowa-Illinois border. The central duck hunting zone is the remainder of the state.

91.1(2) Season dates - north zone.

a. For the 2020-2021 season. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the last Saturday in September and run for 7 days. The second segment of the season will open on the second Saturday in October and continue for 53 consecutive days.

b. For the fall 2021 through spring 2026 seasons. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the Saturday nearest September 30 and run for 7 days. The second segment of the season will open on the Saturday nearest October 13 and continue for 53 consecutive days.

91.1(3) Season dates - south zone/central zone.

a. For the 2020-2021 season - south zone. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the first Saturday in October and run for 7 days. The second segment of the season will open on the third Saturday in October and continue for 53 consecutive days.

b. For the fall 2021 through spring 2026 seasons - central zone. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the Saturday nearest October 6 and run for 7 days. The second segment of the season will open on the Saturday nearest October 20 and continue for 53 consecutive days.

91.1(4) Season dates - Missouri River zone/south zone.

a. For the 2020-2021 season - Missouri River zone. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the second Saturday in October and run for 7 days. The second segment of the season will open on the fourth Saturday in October and continue for 53 consecutive days.

b. For the fall 2021 through spring 2026 seasons - south zone. Special September teal season: September 1 through September 16. For all ducks: The first segment of the season will begin on the Saturday nearest October 13 and run for 7 days. The second segment of the season will open on the Saturday nearest October 27 and continue for 53 consecutive days.

91.1(5) Bag limit. Bag limits for all species other than scaup are as adopted by the U.S. Fish and Wildlife Service and published in the Federal Register. The daily bag limit for scaup will be 1 for the first 15 days of the duck hunting season and 2 for the remaining 45 days.

91.1(6) Possession limit. For the special September teal season and for all ducks: Possession limit is three times the daily bag limit.

91.1(7) Shooting hours. For the special September teal season: Shooting hours are sunrise to sunset each day. For all ducks: Shooting hours are one-half hour before sunrise to sunset each day.

[ARC 8106B, IAB 9/9/09, effective 8/18/09; ARC 9055B, IAB 9/8/10, effective 8/16/10; ARC 9720B, IAB 9/7/11, effective 8/19/11; ARC 0307C, IAB 9/5/12, effective 8/15/12; ARC 1003C, IAB 9/4/13, effective 8/15/13; ARC 1614C, IAB 9/3/14, effective 8/15/14; ARC 2129C, IAB 9/2/15, effective 8/13/15; ARC 2526C, IAB 5/11/16, effective 6/15/16; ARC 3060C, IAB 5/10/17, effective 6/14/17; ARC 3797C, IAB 5/9/18, effective 6/13/18; ARC 5057C, IAB 6/17/20, effective 7/22/20]

571—91.2(481A) Coots (split season). Same as duck season dates and shooting hours.

91.2(1) Bag and possession limits. Daily bag limit is 15 and possession limit is three times the daily bag limit.

91.2(2) Reserved.

[ARC 1003C, IAB 9/4/13, effective 8/15/13]

571—91.3(481A) Goose hunting.

91.3(1) Zone boundaries. The following zone boundaries apply in the time frames noted:

a. For the 2020-2021 season, the north goose hunting zone is that part of Iowa north of a line beginning on the South Dakota-Iowa border at Interstate 29, southeast along Interstate 29 to State Highway 175, east to State Highway 37, southeast to State Highway 183, northeast to State Highway 141, east to U.S. Highway 30, and along U.S. Highway 30 to the Iowa-Illinois border. The Missouri River goose hunting zone is that part of Iowa west of Interstate 29 and south to the Iowa-Missouri border. The south goose hunting zone is the remainder of the state.

b. Effective fall 2021 through spring 2026, the north goose hunting zone is that part of Iowa north of a line beginning on the South Dakota-Iowa border at Interstate 29, southeast along Interstate 29 to State Highway 20 to the Iowa-Illinois border. The south duck hunting zone is that part of Iowa west of Interstate 29 and south of State Highway 92 east to the Iowa-Illinois border. The central duck hunting zone is the remainder of the state.

91.3(2) Season dates - north zone.

a. For the 2020-2021 season. For all geese: The first segment of the regular goose season will begin on the second-to-last Saturday of September and run for a 16-day period. The second segment of the goose season will open on the second Saturday in October and continue for 53 consecutive days. The goose season will then close for a 10-day period and shall then reopen on the following Saturday and remain continuously open until the total number of days used for goose hunting reaches 107.

b. For the fall 2021 through spring 2026 seasons. For all geese: The first segment of the regular goose season will begin on the Saturday nearest September 23 and run for a 16-day period. The second segment of the goose season will open on the Saturday nearest October 13 and continue for 53 consecutive days. The goose season will reopen on the Saturday nearest December 13 and remain continuously open until the total number of days used for goose hunting reaches 107.

91.3(3) Season dates - south zone/central zone.

a. For the 2020-2021 season - south zone. For all geese: The first segment of the regular goose season will begin on the last Saturday of September and run for a 16-day period. The second segment of the goose season will open on the third Saturday in October and continue for 53 consecutive days. The goose season will then close for a 10-day period and shall then reopen on the following Saturday and remain continuously open until the total number of days used for goose hunting reaches 107.

b. For the fall 2021 through spring 2026 seasons - central zone. For all geese: The first segment of the regular goose season will begin on the Saturday nearest September 30 and run for a 16-day period. The second segment of the goose season will open on the Saturday nearest October 20 and continue for 53 consecutive days. The goose season will reopen on the Saturday nearest December 20 and remain continuously open until the total number of days used for goose hunting reaches 107.

91.3(4) Season dates - Missouri River zone/south zone.

a. For the 2020-2021 season - Missouri River zone. For all geese: The first segment of the regular goose season will begin on the first Saturday of October and run for a 16-day period. The second segment of the goose season will open on the fourth Saturday in October and continue for 53 consecutive days.

The goose season will then close for a 10-day period and shall then reopen on the following Saturday and remain continuously open until the total number of days used for goose hunting reaches 107.

b. For the fall 2021 through spring 2026 seasons - south zone. For all geese: The first segment of the regular goose season will begin on the Saturday nearest October 6 and run for a 16-day period. The second segment of the goose season will open on the Saturday nearest October 27 and continue for 53 consecutive days. The goose season will reopen on the Saturday nearest December 27 and remain continuously open until the total number of days used for goose hunting reaches 107.

91.3(5) *Bag limit.* The daily bag limit for dark geese (Canada geese, white-fronted geese, brant and any other geese that are not light geese) is 5 and may include no more than 2 Canada geese from September 16 through October 31 and no more than 3 Canada geese from November 1 through the end of the season. The daily bag limit for light geese (white and blue-phase snow geese and Ross' geese) is 20.

91.3(6) *Possession limit.* The possession limit is three times the daily bag limit for Canada geese, brant and white-fronted geese. There is no possession limit for light geese.

91.3(7) *Shooting hours.* Shooting hours are one-half hour before sunrise until sunset each day.

91.3(8) *Light goose conservation order season.* Only light geese (white and blue-phase snow geese and Ross' geese) may be taken under a conservation order from the U.S. Fish and Wildlife Service beginning the day after the regular goose season closes and continuing until May 1.

a. Zone boundaries. Statewide.

b. Shooting hours. One-half hour before sunrise to one-half hour after sunset.

c. Bag limit. No bag limit.

d. Possession limit. No possession limit.

e. Other regulations. Methods of take approved by the U.S. Fish and Wildlife Service for hunting light geese during the conservation order season shall be permitted.

91.3(9) *Cedar Rapids/Iowa City goose hunting zone.*

a. Season dates. The first Saturday in September for nine consecutive days.

b. Bag limit. Daily bag limit is 5 Canada geese.

c. Possession limit. Three times the daily bag limit.

d. Zone boundary. The Cedar Rapids/Iowa City goose hunting zone includes portions of Linn and Johnson Counties bounded as follows: Beginning at the intersection of the west border of Linn County and Linn County Road E2W; thence south and east along County Road E2W to Highway 920; thence north along Highway 920 to County Road E16; thence east along County Road E16 to County Road W58; thence south along County Road W58 to County Road E34; thence east along County Road E34 to Highway 13; thence south along Highway 13 to Highway 30; thence east along Highway 30 to Highway 1; thence south along Highway 1 to Morse Road in Johnson County; thence east along Morse Road to Wapsi Avenue; thence south along Wapsi Avenue to Lower West Branch Road; thence west along Lower West Branch Road to Taft Avenue; thence south along Taft Avenue to County Road F62; thence west along County Road F62 to Kansas Avenue; thence north along Kansas Avenue to Black Diamond Road; thence west on Black Diamond Road to Jasper Avenue; thence north along Jasper Avenue to Rohert Road; thence west along Rohert Road to Ivy Avenue; thence north along Ivy Avenue to 340th Street; thence west along 340th Street to Half Moon Avenue; thence north along Half Moon Avenue to Highway 6; thence west along Highway 6 to Echo Avenue; thence north along Echo Avenue to 250th Street; thence east on 250th Street to Green Castle Avenue; thence north along Green Castle Avenue to County Road F12; thence west along County Road F12 to County Road W30; thence north along County Road W30 to Highway 151; thence north along the Linn-Benton County line to the point of beginning.

91.3(10) *Des Moines goose hunting zone.*

a. Season dates. The first Saturday in September for nine consecutive days.

b. Bag limit. Daily bag limit is 5 Canada geese.

c. Possession limit. Three times the daily bag limit.

d. Zone boundary. The Des Moines goose hunting zone includes those portions of Polk, Warren, Madison and Dallas Counties bounded as follows: Beginning at the intersection of Northwest 158th Avenue and County Road R38 in Polk County; thence south along County Road R38 to Northwest

142nd Avenue; thence east along Northwest 142nd Avenue to Northeast 126th Avenue; thence east along Northeast 126th Avenue to Northeast 46th Street; thence south along Northeast 46th Street to Highway 931; thence east along Highway 931 to Northeast 80th Street; thence south along Northeast 80th Street to Southeast 6th Avenue; thence west along Southeast 6th Avenue to Highway 65; thence south and west along Highway 65 to Highway 69 in Warren County; thence south along Highway 69 to County Road G24; thence west along County Road G24 to Highway 28; thence southwest along Highway 28 to 43rd Avenue; thence north along 43rd Avenue to Ford Street; thence west along Ford Street to Filmore Street; thence west along Filmore Street to 10th Avenue; thence south along 10th Avenue to 155th Street in Madison County; thence west along 155th Street to Cumming Road; thence north along Cumming Road to Badger Creek Avenue; thence north along Badger Creek Avenue to County Road F90 in Dallas County; thence east along County Road F90 to County Road R22; thence north along County Road R22 to Highway 44; thence east along Highway 44 to County Road R30; thence north along County Road R30 to County Road F31; thence east along County Road F31 to Highway 17; thence north along Highway 17 to Highway 415 in Polk County; thence east along Highway 415 to Northwest 158th Avenue; thence east along Northwest 158th Avenue to the point of beginning.

91.3(11) Cedar Falls/Waterloo goose hunting zone.

a. *Season dates.* The first Saturday in September for nine consecutive days.

b. *Bag limit.* Daily bag limit is 5 Canada geese.

c. *Possession limit.* Three times the daily bag limit.

d. *Zone boundary.* The Cedar Falls/Waterloo goose hunting zone includes those portions of Black Hawk County bounded as follows: Beginning at the intersection of County Roads C66 and V49 in Black Hawk County, thence south along County Road V49 to County Road D38, thence west along County Road D38 to State Highway 21, thence south along State Highway 21 to County Road D35, thence west along County Road D35 to Grundy Road, thence north along Grundy Road to County Road D19, thence west along County Road D19 to Butler Road, thence north along Butler Road to County Road C57, thence north and east along County Road C57 to U.S. Highway 63, thence south along U.S. Highway 63 to County Road C66, thence east along County Road C66 to the point of beginning.

[ARC 8106B, IAB 9/9/09, effective 8/18/09; ARC 9055B, IAB 9/8/10, effective 8/16/10; ARC 9720B, IAB 9/7/11, effective 8/19/11; ARC 0307C, IAB 9/5/12, effective 8/15/12; ARC 1003C, IAB 9/4/13, effective 8/15/13; ARC 1614C, IAB 9/3/14, effective 8/15/14; ARC 2129C, IAB 9/2/15, effective 8/13/15; ARC 2526C, IAB 5/11/16, effective 6/15/16; ARC 3060C, IAB 5/10/17, effective 6/14/17; ARC 3797C, IAB 5/9/18, effective 6/13/18; ARC 5057C, IAB 6/17/20, effective 7/22/20]

571—91.4(481A) Closed areas. Waterfowl and coots may be hunted statewide except in specific areas.

91.4(1) Waterfowl and coots. There shall be no open season for ducks, coots and geese on the east and west county road running through sections 21 and 22, township 70 north, range 43 west, Fremont County; three miles of U.S. Highway 30, located on the south section lines of sections 14, 15, and 16, township 78 north, range 45 west, Harrison County; on the county roads immediately adjacent to, or through, Union Slough National Wildlife Refuge, Kossuth County; Louisa County Road X61 from the E-W centerline of section 29, township 74 north, range 2 west, on the south, to the point where it crosses Michael Creek in section 6, township 74 north, range 2 west, on the north, and also all roads through or adjacent to sections 7, 18, and 19 of this same township and roads through or adjacent to sections 12 and 13, township 74 north, range 3 west; the levee protecting the Green Island Wildlife Area from the Mississippi River in Jackson County wherever the levee is on property owned by the United States or the state of Iowa; certain dikes at Otter Creek Marsh, Tama County, where posted as such; and the NE $\frac{1}{4}$, section 23, and the N $\frac{1}{2}$, section 24, all in township 70 north, range 19 west, Appanoose County, including county roads immediately adjacent thereto; and all privately owned lands in the S $\frac{1}{2}$, section 30, township 71 north, range 20 west, Lucas County, including the county road immediately adjacent thereto; Cerro Gordo County Road S14 and its right-of-way, between its junction with U.S. Highway 18 and County Road B-35, and portions of Clear Lake and Ventura Marsh, where posted as such in Cerro Gordo County; that portion of Summit Lake located south of State Highway 25 in the west half of the NW $\frac{1}{4}$ of section 2 (22 acres), and the west half of section 3 (100 acres), T72N, R31W in Union County; and within 150 feet of the center of the Army Road from New Albin to the boat ramp on the Mississippi River in sections 11 and 12, T100N, R4W, and sections 7 and 8, T100N, R3W, as posted.

91.4(2) *Canada geese.* There shall be no open season on Canada geese in certain areas described as follows:

a. Area one. Portions of Emmet County bounded as follows: Beginning at the northwest corner of section 3, township 98 north, range 33 west; thence east on the county road a distance of five miles; thence south on the county road a distance of three and one-half miles; thence west on the county road a distance of four miles; then continuing west one mile to the southwest corner of the northwest one-quarter of section 22, township 98 north, range 33 west; thence north on the county road to the point of beginning.

b. Area two. Portions of Clay and Palo Alto Counties bounded as follows: Beginning at the junction of County Roads N14 and B17 in Clay County, thence south four miles on N14 (including the road right-of-way), thence east one-half mile, thence east one mile on a county road, thence north one mile on a county road, thence east one mile on a county road to County Road N18, thence south and east approximately one mile on N18, thence east one and one-half miles on a Palo Alto County Road, thence north two miles on a county road, thence east approximately one and one-half miles on a county road, thence north two miles on a county road to County Road B17, thence west six miles to the point of beginning.

c. Area three. A portion of Dickinson County bounded as follows: Beginning at the junction of State Highways 9 and 86; thence north along State Highway 86 (including the right-of-way) to the Iowa-Minnesota state line; thence east along the Iowa-Minnesota state line approximately 3.5 miles (excluding any road right-of-ways) to 240th Avenue (also known as West Lake Shore Drive in Orleans or Peoria Avenue in Spirit Lake); thence south along 240th Avenue (including the right-of-way) to State Highway 9; thence west along State Highway 9 (including the right-of-way) to the point of beginning.

d. Area four. Portions of Winnebago and Worth Counties bounded as follows: Beginning at the junction of U.S. Highway 69 and County Road 105 in the city of Lake Mills; thence east along County Road 105 (including the right-of-way and all other road right-of-ways identified in this description) approximately 2 miles to Apple Ave.; thence south along Apple Ave. to 448th St.; thence east two and one-fourth miles on 448th St. to Cardinal Ave.; thence south one-fourth mile to 445th St.; thence east one-fourth mile to Cedar Ave.; thence south one-half mile on Cedar Ave. to the intersection of Cedar Ave. and 440th St.; thence south one-half mile across the north half of section 16, township 99 north, range 22 west, to the intersection of Cedar Ave. and 435th St.; thence south 2 miles along Cedar Ave. to Lake St.; thence west one-fourth mile along Lake St. to Front St.; thence southeast one-half mile along Front St. to County Road A38 (also named 410th St.); thence west along County Road A38 to County Road R74 (also named 225th Ave.); thence north along County Road R74 to 420th St.; thence west along 420th St. to 220th Ave.; thence north along 220th Ave. to 430th St.; thence west along 430th St. one-half mile; thence north one mile across section 15, township 99 north, range 23 west, to the intersection of 440th St. and 215th Ave.; thence north one-fourth mile on 215th Ave. to 445th St.; thence east and northeast on 445th St. to South 12th Ave. West in Lake Mills; thence east on South 12th Ave. West to South Lake St.; thence north on South Lake St. to point of beginning.

e. Area five. On any federal or state-owned lands or waters within the area bounded by the following roads: Beginning at the junction of Lucas County Road S56 and 400th Street; thence west on 400th Street to its intersection with 291st Avenue; thence north on 291st Avenue to its intersection with 410th Street; thence west on 410th Street to its intersection with 280th Avenue; thence north on 280th Avenue to its intersection with 430th Street; thence east on 430th Street to its intersection with 290th Trail; thence south and east on 290th Trail to its intersection with Lucas County Road S56; thence south on Lucas County Road S56 to the point of beginning, including all federal, state, and county roads through or immediately adjacent thereto.

f. Area six. Rescinded IAB 8/31/05, effective 8/11/05.

g. Area seven. Portions of Guthrie and Dallas Counties bounded as follows: Beginning at the junction of State Highways 4 and 44 in Panora; thence north along State Highway 4 (including the right-of-way) to County Road F25; thence east along County Road F25 (including the right-of-way) to York Avenue; thence south along York Avenue 1 mile (including the right-of-way) to 170th Street; thence east one-half mile (including the right-of-way) to A Avenue in Dallas County; thence south on A

Avenue 5 miles (including the right-of-way) to State Highway 44; thence west along State Highway 44 (including the right-of-way) to the point of beginning.

h. Area eight. A portion of Adams County bounded as follows: Beginning at the intersection of State Highway 148 and Adams County Road N28; thence east along Adams County Road N28 (including the right-of-way) to Adams County Road N53; thence east and north along Adams County Road N53 (including the right-of-way) approximately 4.5 miles to Adams County Road H24; thence west along Adams County Road H24 (including the right-of-way) about 8 miles to Hickory Avenue; thence south along Hickory Avenue (including the right-of-way) about 2.5 miles to Adams County Road N28; thence east along Adams County Road N28 (including the right-of-way) to the point of beginning.

i. Area nine. Portions of Monona and Woodbury Counties bounded as follows: For the portion in Monona County, beginning at the junction of County Road K42 and 120th Street; thence south along County Road K42 (including the right-of-way and all other road right-of-ways identified in this description) approximately 4 miles; thence south on Berry Avenue approximately 1 mile to 170th Street; thence east along 170th Street to Cork Avenue; thence north along Cork Avenue to County Road K45; thence northwest approximately 2 miles along County Road K45 to 120th Street; thence west along 120th Street to the point of beginning; and for the portion in Woodbury County, beginning at the junction of County Road K42 and Interstate 29; thence northwest along Interstate 29 approximately 6 miles to the intersection with Woodbury County Road K25; thence west approximately 2 miles along Woodbury County Road K25 to the intersection with Port Neal Road; thence continuing along the same westerly line approximately 1 mile on the north border of section 6, township 86 north, range 47 west, to the center of the Missouri River; thence southerly along the Missouri River channel approximately 8 miles to a point where 340th Street meets the Iowa-Nebraska state line on the Missouri River except that portion of Nebraska lying on the east side of the Missouri River; thence east to and along 340th Street approximately 5.5 miles to County Road K42; thence north and east along County Road K42 approximately 1.5 miles to the point of beginning.

j. Area ten. Rescinded IAB 9/5/01, effective 8/17/01.

k. Area eleven. Starting at the junction of the navigation channel of the Mississippi River and the mouth of the Maquoketa River in Jackson County, proceeding southwesterly along the high-water line on the west side of the Maquoketa River to U.S. Highway 52; thence southeast along U.S. Highway 52 (including the right-of-way) to 607th Avenue; thence east along 607th Avenue (including the right-of-way) to the Sioux Line Railroad; thence north and west along the Sioux Line Railroad to the Green Island levee; thence northeast along a line following the Green Island levee to the center of the navigational channel of the Mississippi River; thence northwest along the center of the navigational channel to the point of beginning.

l. Area twelve. Rescinded IAB 8/30/06, effective 8/11/06.

m. Area thirteen. Portions of Van Buren County bounded as follows: Beginning at the junction of State Highway 2 and State Highway 1; thence west on State Highway 2 to County Road V64 (including the right-of-way and all other road right-of-ways identified in this description); thence north on County Road V64 to County Road J40; thence east on County Road J40 to State Highway 1; thence south on State Highway 1 to the point of beginning.

n. Area fourteen. Portions of Bremer County bounded as follows: Beginning at the intersection of Tahoe Avenue and State Highway 93 (also named 140th Street); thence south along Tahoe Avenue (including the right-of-way and all other road right-of-ways identified in this description) to County Road C33; thence west along County Road C33 to Navaho Avenue; thence north along Navaho Avenue to State Highway 93; thence west along State Highway 93 to U.S. Highway 63; thence north 3 miles along U.S. Highway 63 to 140th Street; thence east along 140th Street for 2 miles and continuing on a similar east line for 2 more miles along the north borders of sections 28 and 29, township 93 north, range 12 west, to County Road V5C (also named 140th Street); thence east about one-half mile on County Road V5C to State Highway 93; thence east on State Highway 93 to the point of beginning.

o. Area fifteen. Portions of Butler County bounded as follows: Beginning at the junction of State Highway 14 and 245th Street; thence south along State Highway 14 (including the right-of-way and all other road right-of-ways identified in this description) to 280th Street; thence west along 280th Street for

3 miles; continuing on a similar westerly line along the south border of section 32, township 91 north, range 17 west, to County Road T25 (also named Hickory Avenue); thence north along County Road T25 to 230th Street; thence east along 230th Street to Jackson Avenue; thence south along Jackson Avenue to 240th Street; thence east along 240th Street to Jackson Avenue; thence south on Jackson Avenue to 245th Street; thence east along 245th Street to the point of beginning.

p. Area sixteen. A portion of Union County bounded as follows: Beginning at the intersection of U.S. Highway 34 and County Road P53 near Afton; thence west along U.S. Highway 34 (including the right-of-way and all other road right-of-ways identified in this description) approximately 2.5 miles to Twelve Mile Lake Road; thence north along Twelve Mile Lake Road approximately 5 miles to Union County Road H17; thence north and east along Union County Road H17 to County Road P53; thence south along County Road P53 to the point of beginning.

q. Area seventeen. Rescinded IAB 9/1/04, effective 8/13/04.

91.4(3) Forney Lake. The entire Forney Lake area, in Fremont County, north of the east-west county road, shall be closed to waterfowl hunting prior to the opening date for taking geese on the area each year.

[ARC 8106B, IAB 9/9/09, effective 8/18/09; ARC 0307C, IAB 9/5/12, effective 8/15/12; ARC 3060C, IAB 5/10/17, effective 6/14/17]

571—91.5(481A) Canada goose hunting within closed areas.

91.5(1) Closed areas. All areas described in subrule 91.4(2).

a. Purpose. The hunting of Canada geese in closed areas is being undertaken to allow landowners or tenants who farm in these closed areas to hunt Canada geese on land they own or farm in the closed area.

b. Criteria.

(1) Landowners and tenants who own or farm land in the closed areas will be permitted to hunt Canada geese in the closed areas for three years. This experimental hunting opportunity will be evaluated by the landowners and the DNR following each season, at which time changes may be made.

(2) Landowners and those individuals named on the permit according to the criteria specified in paragraph (9) of this subrule will be permitted to hunt in the closed area. Tenants may obtain a permit instead of the landowner if the landowner transfers this privilege to the tenant. Landowners may choose, at their discretion, to include the tenant and those individuals of the tenant's family specified in paragraph (9) of this subrule on their permit. Landowners may assign the permit for their land to any landowner or tenant who owns or farms at least eight acres inside the closed area. Assigned permits must be signed by both the permittee and the landowner assigning the permit.

(3) Landowners must hold title to, or tenants must farm by a rent/share/lease arrangement, at least eight acres inside the closed area to qualify for a permit.

(4) No more than one permit will be issued to corporations, estates, or other legal associations that jointly own land in the closed area. No individual may obtain more than two permits nor may an individual be named as a participant on more than two permits.

(5) Persons holding a permit can hunt with those individuals named on their permit as specified in paragraph (9) of this subrule on any property they own (or rent/share/lease in the case of tenants) in the closed area provided their activity complies with all other regulations governing hunting. Nothing herein shall permit the hunting of Canada geese on public property within the closed area.

(6) Persons hunting under this permit must adhere to all municipal, county, state and federal regulations that are applicable to hunting and specifically applicable to Canada goose hunting including, but not limited to: daily limits, possession limits, shooting hours, methods of take, and transportation. Hunting as authorized by this rule shall not be used to stir or rally waterfowl.

(7) Hunting within the closed area will be allowed through October 31.

(8) Permit holders will be allowed to take eight Canada geese per year in the closed area.

(9) Permits will be issued only to individual landowners or tenants; however, permit holders must specify, when requesting a permit, the names of all other individuals qualified to hunt on the permit. Individuals qualified to hunt on the permit shall include the landowners or tenants and their spouses,

domestic partners, parents, grandparents, children, children's spouses, grandchildren, siblings and siblings' spouses only.

c. Procedures.

(1) Permits can be obtained from the local conservation officer at the wildlife unit headquarters within the closed area at announced times, but no later than 48 hours before the first Canada goose season opens. The permit will be issued to an individual landowner or tenant and must list the names of all individuals that may hunt with the permittee. The permit will also contain a description of the property covered by the permit. The permit must be carried by a member of the hunting party whose name is listed on the permit. Conservation officers will keep a record of permittees and locations of properties that are covered by permits.

(2) Eight consecutively numbered tags will be issued with each permit. Geese will be tagged around the leg immediately upon being reduced to possession and will remain tagged until delivered to the person's abode. Within one week of the close of hunting within the closed area during at least the first three years the hunt is permitted, unused tags must be turned in at the wildlife unit headquarters within the closed area or the permittee must report the number of geese killed. Failure to turn in unused tags or report the number of geese killed within the specified time period may result in the permittee's forfeiting the opportunity to hunt within the closed area the following year.

(3) No one may attempt to take Canada geese under this permit unless the person possesses an unused tag for the current year.

(4) No landowner or tenant shall be responsible or liable for violations committed by other individuals listed on the permit issued to the landowner or tenant.

91.5(2) Reserved.

[ARC 8106B, IAB 9/9/09, effective 8/18/09; ARC 0307C, IAB 9/5/12, effective 8/15/12]

571—91.6(481A) Youth waterfowl hunt. A special youth waterfowl hunt will be held the weekend before the first segment of the regular duck season in each duck hunting zone. Youth hunters must be residents of Iowa as defined in Iowa Code section 483A.1A and less than 16 years old. Each youth hunter must be accompanied by an adult 18 years old or older. The youth hunter does not need to have a hunting license or stamps. The adult must have a valid hunting license and habitat stamp if normally required to have them to hunt and a state waterfowl stamp. Only the youth hunter may shoot ducks and coots. The adult may hunt for any game birds for which the season is open. The daily bag and possession limits are the same as for the regular waterfowl season, as defined in rule 571—91.1(481A). All other hunting regulations in effect for the regular waterfowl season apply to the youth hunt.

[ARC 8106B, IAB 9/9/09, effective 8/18/09; ARC 9055B, IAB 9/8/10, effective 8/16/10; ARC 9720B, IAB 9/7/11, effective 8/19/11; ARC 0307C, IAB 9/5/12, effective 8/15/12; ARC 1003C, IAB 9/4/13, effective 8/15/13; ARC 1614C, IAB 9/3/14, effective 8/15/14; ARC 2129C, IAB 9/2/15, effective 8/13/15; ARC 2526C, IAB 5/11/16, effective 6/15/16; ARC 3060C, IAB 5/10/17, effective 6/14/17; ARC 3797C, IAB 5/9/18, effective 6/13/18]

These rules are intended to implement Iowa Code sections 481A.38, 481A.39, and 481A.48.

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CHAPTER 113
RESTITUTION FOR POLLUTION CAUSING INJURY TO WILD ANIMALS

571—113.1(481A) Applicability. These rules apply to persons who cause, by water pollution, the destruction of or injury to wild animals held in trust by the state for the public. In most cases this would involve the destruction of aquatic life or other wildlife under the ownership of the state, as provided in Iowa Code section 481A.2. These rules relate to the compensation to the state and public for the natural resource damages and are in addition to any other legal recourse for the event or action that caused the destruction or damage. The administration of this chapter shall not result in a duplication of damages collected by the department under Iowa Code section 455B.392, subsection 1, paragraph “c.”

571—113.2(481A) Definitions.

“*AFS*” means the Special Publication 35, “Investigation and Monetary Values of Fish and Freshwater Mollusk Kills,” published by the American Fisheries Society.

“*Damages*” means the costs of restoration, rehabilitation, and replacement of resources or acquisition of equivalent resources, as determined in accordance with this chapter; the reasonable and necessary costs of the assessment, to include the cost of performing the assessment and administrative costs and expenses necessary for, and incidental to, the assessment; lost services to the public; and, in the event the damages claim is not resolved within six months after the incident leading to the damages, interest at the current rate published in the Iowa Administrative Bulletin by the department of revenue pursuant to Iowa Code section 421.7. The interest amount shall be computed from the date the amount of the claim is confirmed by a final ruling of the commission in a contested case decision.

“*Priority watershed*” means a watershed for which:

1. The department of natural resources, in partnership with other state or federal agencies, the agriculture community or nonprofit organizations, creates and implements plans, programs or projects to sustain and enhance watershed and stream functions; and
2. The principal objective is to manage wild animals and their habitats.

“*Surface water resources*” means the waters of the state, including the sediments suspended in water or lying on the bank, bed, or shoreline. This term does not include groundwater or water or sediments in ponds, lakes, or reservoirs designed for waste treatment under applicable laws regulating waste treatment.

“*Wild animals*” means fish, wildlife and other biota belonging to, managed by, held in trust by, appertaining to, or otherwise controlled by the state of Iowa, the United States, or local government. Fish and wildlife include freshwater aquatic and terrestrial species; game, nongame, and commercial species; and threatened and endangered species. Other biota encompass shellfish and other living organisms not otherwise listed in this definition.

[ARC 8464B, IAB 1/13/10, effective 2/17/10; ARC 9054B, IAB 9/8/10, effective 10/13/10; ARC 5058C, IAB 6/17/20, effective 7/22/20]

571—113.3(481A) Liability to the state. Persons who cause by water pollution the destruction of or injury to wild animals of the state shall be liable to the state as provided in Iowa Code section 481A.151. These rules establish the methodologies and criteria for evaluating the extent and value of the destruction or injury and establish the methods of compensation. If the person and the department cannot agree to the proper resolution of a particular case, the issues of liability, damage and compensation will be established through contested case proceedings, as provided by 571—Chapter 7.

[ARC 8464B, IAB 1/13/10, effective 2/17/10]

571—113.4(481A) Assessment. When wild animals are destroyed or injured by an identifiable source of water pollution, the degree and value of the losses shall be assessed by collecting, compiling, and analyzing relevant information, statistics, or data through prescribed methodologies to determine damages, as set forth in this rule.

113.4(1) General. For species other than fish, the professional judgment of fish and wildlife staff and available literature and guidance normally relied on in the fish and wildlife professions may be used to assess the injuries.

113.4(2) Fish loss. Assessment of damages for fish kills shall be in accordance with the following:

a. Normally investigators will follow the methods prescribed by AFS to determine, by species and size, numbers of fish killed.

b. During periods of ice cover, where local conditions prevent using the methods in “*a*” above, or in other appropriate circumstances, for example, when the resources are known to have been diminished by prior incidents, investigators will utilize the best information available to determine, by species and size, numbers of fish killed. Information may include existing or prior data on population levels in the affected water body or a nearby water body with similar characteristics, including any historical fish kill data.

c. The monetary valuation of fish shall be the replacement values as published in AFS for all fish lost except the following: channel catfish, flathead catfish, blue catfish, northern pike, muskellunge, northern pike/muskellunge hybrid, rainbow trout, brown trout, brook trout, white bass, yellow bass, white bass/striped bass hybrid, largemouth bass, smallmouth bass, spotted bass, crappie, rock bass, bluegill, redear sunfish, warmouth, pumpkinseed, freshwater drum, yellow perch, walleye, sauger and walleye/sauger hybrid. The value of these fish shall be \$15 each, unless AFS establishes a higher value. Notwithstanding the above, the value of each fish classified by the department as an endangered or threatened species shall be \$1,000.

d. The value of lost services to the public shall be the number of fishing trips lost over the period of the resource loss, as determined through local creel survey information or through interpolation from the most recent statewide creel survey. Each trip shall be valued at \$30.

e. The cost of the investigation shall include:

(1) Salaries plus overhead of staff, including support staff, involved in investigating the fish kill and performing the assessment.

(2) Any meals and lodging of staff while they are in the field conducting the assessment.

(3) Mileage valued at the current rate established pursuant to Iowa Code section 18.117.

(4) Costs borne by the department associated with containment or cleanup operations.

(5) Any other costs directly associated with the investigation and assessment.

[ARC 8464B, IAB 1/13/10, effective 2/17/10]

571—113.5(481A) Compensation. The department will extend to the responsible person the opportunity to reach voluntary agreement as to the amount of damages and the compensation method. The method of compensation shall be solely in the discretion of the department. If the person disputes liability or the damage amount, these issues will be resolved through contested case proceedings.

113.5(1) Direct monetary payment. Compensation shall normally be by direct monetary payment to the department for projects in priority watersheds selected by the department. To the extent reasonable and practical, the money received will be used to replace, restore or rehabilitate the lost or injured animals. Resource enhancement projects, support of educational programs relating to resource protection or enhancement, or resource acquisition of equal or greater value also may be funded. If practical, such alternatives should provide similar services to the public.

113.5(2) Indirect monetary payment. In cases where the destruction of or injury to wild animals is in a selected priority watershed, an equal or greater amount of compensation may be made by monetary payment to another government agency or private nonprofit group in the natural resource field for the same purposes as provided in subrule 113.5(1).

113.5(3) Direct funding of projects. With the approval and oversight of the department, the person may be allowed to contract directly for the same purposes as provided in subrule 113.5(1).

[ARC 9054B, IAB 9/8/10, effective 10/13/10]

These rules are intended to implement Iowa Code sections 456A.23, 481A.2 and 481A.151.

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PUBLIC HEALTH DEPARTMENT[641]

Rules of divisions under this department “umbrella” include Professional Licensure[645], Dental Board[650], Medical Board[653],
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641—37.1(136C) Purpose and scope.

37.1(1) This chapter has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this chapter. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this chapter authorizes possession of licensed material.

37.1(2) The divisions in this chapter entitled “Background Investigations and Access Control Program” and “Physical Protection Requirements During Use,” including rules 641—37.21(136C) to 641—37.57(136C), apply to any person who, under the regulations in this chapter, possesses or uses at any site an aggregated category 1 or category 2 quantity of radioactive material.

37.1(3) The division in this chapter entitled “Physical Protection in Transit,” including rules 641—37.71(136C) to 641—37.81(136C), applies to any person who, under the rules of this chapter:

- a. Transports or delivers to a carrier for transport in a single shipment a category 1 or category 2 quantity of radioactive material; or
- b. Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

37.1(4) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—37.2 to 37.4 Reserved.

641—37.5(136C) Definitions.

37.5(1) For the purposes of this chapter, these terms have the definitions set forth below.

“*Access control*” means a system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

“*Act*” means the Atomic Energy Act of 1954 (68 Stat. 919), as amended through July 16, 2014.

“*Agency*” means the Iowa department of public health.

“*Aggregated*” means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

“*Agreement state*” means any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under Subsection 274b. of the Act. “*Non-agreement state*” means any other state.

“*Approved individual*” means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with rules 641—37.21(136C) through 641—37.33(136C) and who has completed the training required by 37.43(3).

“*Background investigation*” means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

“*Becquerel (Bq)*” means one disintegration per second.

“*Byproduct material*” means:

1. Any radioactive material, except special nuclear material, yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “byproduct material” within this definition;

3. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or any material that:

- Has been made radioactive by use of a particle accelerator; and
- Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

- The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

- Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

“*Carrier*” means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

“*Category 1 quantity of radioactive material*” means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this chapter. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

“*Category 2 quantity of radioactive material*” means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this chapter. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

“*Commission*” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

“*Curie*” means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

“*Diversions*” means the unauthorized movement of radioactive material subject to this chapter to a location different from the material’s authorized destination inside or outside of the site at which the material is used or stored.

“*Escorted access*” means accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

“*Fingerprint orders*” means the orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

“*Government agency*” means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the government.

“*License*” means a license issued by the agency in accordance with the rules adopted by the agency.

“License-issuing authority” means the licensing agency that issued the license, i.e., the agency, the U.S. Nuclear Regulatory Commission or an agreement state.

“Local law enforcement agency (LLEA)” means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

“Lost or missing licensed material” means licensed material whose location is unknown. Lost or missing licensed material includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

“Mobile device” means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismantling; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

“Movement control center” means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

“No-later-than arrival time” means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

“Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

“Reviewing official” means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

“Sabotage” means deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

“Safe haven” means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

“Security zone” means any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

“State” means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

“Telemetric position monitoring system” means a data transfer system that captures information by instrumentation or measuring devices, or both, about the location and status of a transport vehicle or package between the departure and destination locations.

“Trustworthiness and reliability” are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

“Unescorted access” means solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

“*United States*,” when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.6 Reserved.

641—37.7(136C) Communications. All communications and reports concerning the rules in this chapter should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.8 to 37.10 Reserved.

641—37.11(136C) Specific exemptions.

37.11(1) The agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this chapter as it determines are authorized by law and will not result in undue hazard to public health and safety or property and are otherwise in the public interest. Application for exemption should be made in accordance with 641—Chapter 178.

37.11(2) A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of this chapter. Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this chapter. The licensee shall implement the following requirements to secure the radioactive waste:

a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

b. Use a locked door or gate with monitored alarm at the access control point;

c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

d. Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.12 to 37.20 Reserved.

BACKGROUND INVESTIGATIONS AND ACCESS CONTROL PROGRAM

641—37.21(136C) Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

37.21(1) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this chapter.

37.21(2) An applicant for a new license and each licensee that would become newly subject to the requirements of this chapter upon application for amendment of its license, and a licensee aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold, shall implement the requirements of this chapter and be inspected by the agency, as appropriate, before a new license or license amendment will be issued.

37.21(3) The licensee’s access authorization program must ensure that the individuals specified in 37.21(4) are trustworthy and reliable.

37.21(4) Applicability.

a. Licensees shall subject the following individuals to an access authorization program:

(1) Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(2) Reviewing officials.

b. Licensees need not subject the categories of individuals listed in rule 641—37.29(136C) to the investigation elements of the access authorization program.

c. Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

d. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under these rules.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.22 Reserved.

641—37.23(136C) Access authorization program requirements.

37.23(1) Granting unescorted access authorization.

a. Licensees shall implement the requirements of these rules for granting initial or reinstated unescorted access authorization.

b. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by 37.43(3) before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

37.23(2) Reviewing officials.

a. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

b. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Each licensee shall provide oath or affirmation certifications to the agency in accordance with rule 641—37.7(136C). The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. Every ten years, the licensee shall recertify that the reviewing official is deemed trustworthy and reliable in accordance with 37.25(3).

c. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

d. Reviewing officials cannot approve other individuals to act as reviewing officials.

e. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(1) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(2) The individual is subject to a category listed in rule 641—37.29(136C).

37.23(3) Informed consent.

a. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of 37.25(2). A signed consent must be obtained prior to any reinvestigation.

b. The subject individual may withdraw the individual's consent at any time. Licensees shall inform the individual that:

(1) If an individual withdraws consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew consent; and

(2) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

37.23(4) *Personal history disclosure.* Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by these rules is sufficient cause for denial or termination of unescorted access authorization.

37.23(5) *Determination basis.*

a. The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of these rules.

b. The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of these rules and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

c. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

d. The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

e. Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

37.23(6) *Procedures.* Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

37.23(7) *Right to correct and complete information.*

a. Prior to any final adverse determination, licensees shall provide each individual subject to these rules with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one year from the date of the notification.

b. If, after reviewing the individual's criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306, as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any changes necessary in accordance

with the information supplied by that agency. Licensees must provide at least ten days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record is made available for the individual's review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

37.23(8) Records.

a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

b. The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

c. The licensee shall retain the list of persons approved for unescorted access authorization for three years after the list is superseded or replaced.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—37.24 Reserved.

641—37.25(136C) Background investigations.

37.25(1) Initial investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

a. Fingerprinting and an FBI identification and criminal history records check in accordance with rule 641—37.27(136C);

b. Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who the applicant claims to be. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with rule 641—37.31(136C). Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

c. Employment history verification. Licensees shall complete employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

d. Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

e. Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this rule must be limited to whether the individual has been and continues to be trustworthy and reliable;

f. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

g. If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten business

days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation and shall attempt to obtain the information from an alternate source.

37.25(2) Grandfathering.

a. Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the fingerprint orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

b. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk-significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

37.25(3) Reinvestigations. Licensees shall conduct a reinvestigation every ten years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with rule 641—37.27(136C). The reinvestigations must be completed within ten years of the date on which these elements were last completed.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.26 Reserved.

641—37.27(136C) Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

37.27(1) General performance objective and requirements.

a. Except for those individuals listed in rule 641—37.29(136C) and those individuals grandfathered under 37.25(2), each licensee subject to the provisions of these rules shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

b. The licensee shall notify each affected individual that the individual's fingerprints will be used to secure a review of the individual's criminal history record, and shall inform the individual of the procedures for revising the record or adding explanations to the record.

c. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(1) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of the individual's unescorted access authorization; and

(2) The previous access was terminated under favorable conditions.

d. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under these rules, the fingerprint orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of 37.31(3).

e. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

37.27(2) Prohibitions.

a. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

- (1) An arrest more than one year old for which there is no information of the disposition of the case; or
- (2) An arrest that resulted in dismissal of the charge or an acquittal.

b. Licensees may not use information received from a criminal history records check obtained under these rules in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

37.27(3) Procedures for processing of fingerprint checks.

a. For the purpose of complying with these rules, licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-8B20, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at www.nrc.gov/security/chp.html.

b. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?")

c. The Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—37.28 Reserved.

641—37.29(136C) Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

37.29(1) Fingerprinting, identification, and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended through July 16, 2014, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

- a.* An employee of the Nuclear Regulatory Commission or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;
- b.* A member of Congress;
- c.* An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

- d.* The governor of a state or the governor's designated state employee representative;
- e.* Federal, state, or local law enforcement personnel;
- f.* State radiation control program directors and state homeland security advisors or their designated state employee representatives;
- g.* Agreement state employees conducting security inspections on behalf of the NRC under an agreement executed under Section 274.i. of the Atomic Energy Act;
- h.* Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;
- i.* Emergency response personnel who are responding to an emergency;
- j.* Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;
- k.* Package handlers at transportation facilities such as freight terminals and railroad yards;
- l.* Any individual who has an active federal security clearance, provided that the individual makes available the appropriate documentation. Written confirmation from the agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and
- m.* Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

37.29(2) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended through July 16, 2014, are not required for an individual who has had a favorably adjudicated U.S. government criminal history records check within the last five years, under a comparable U.S. government program involving fingerprinting and an FBI identification and criminal history records check provided that the individual makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

- a.* National Agency Check;
- b.* Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;
- c.* Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;
- d.* Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;
- e.* Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and
- f.* Customs and Border Protection's Free and Secure Trade (FAST) Program.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 3746C, IAB 4/11/18, effective 5/16/18]

641—37.30 Reserved.

641—37.31(136C) Protection of information.

37.31(1) Each licensee who obtains background information on an individual under these rules shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

37.31(2) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, the individual's representative, or to those who have a need

to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

37.31(3) The personal information obtained on an individual from a background investigation may be provided to another licensee:

a. Upon the individual's written request to the licensee holding the data to disseminate the information contained in the individual's file; and

b. If the recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

37.31(4) The licensee shall make background investigation records obtained under these rules available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

37.31(5) The licensee shall retain all fingerprint and criminal history records on an individual (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, for three years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.32 Reserved.

641—37.33(136C) Access authorization program review.

37.33(1) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of these rules and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall, at 12-month intervals, review the access program content and implementation.

37.33(2) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

37.33(3) Review records must be maintained for three years.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.34 to 37.40 Reserved.

PHYSICAL PROTECTION REQUIREMENTS DURING USE

641—37.41(136C) Security program.

37.41(1) Applicability.

a. Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of rules 641—37.41(136C) to 641—37.57(136C).

b. An applicant for a new license and a licensee that would become newly subject to the requirements of this chapter upon application for amendment of its license shall implement the requirements of this chapter and be inspected by the agency, as appropriate, before a new license or license amendment will be issued.

c. Any licensee that has not previously implemented the security orders or been subject to the provisions of these rules shall provide written notification to the agency as specified in rule

641—37.7(136C) at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

37.41(2) *General performance objective.* Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

37.41(3) *Program features.* Each licensee's security program must include the program features, as appropriate, described in this chapter.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 3746C, IAB 4/11/18, effective 5/16/18]

641—37.42 Reserved.

641—37.43(136C) General security program requirements.

37.43(1) *Security plan.*

a. Each licensee identified in 37.41(1)“a” shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by these rules.

The security plan must, at a minimum:

- (1) Describe the measures and strategies used to implement the requirements of these rules; and
- (2) Identify the security resources, equipment, and technology used to satisfy the requirements of these rules.

b. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

c. A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that:

- (1) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and
- (2) The affected individuals are instructed on the revised plan before the changes are implemented.

d. The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

37.43(2) *Implementing procedures.*

a. The licensee shall develop and maintain written procedures that document how the requirements of these rules and the security plan will be met.

b. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

c. The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three years after the record is superseded.

37.43(3) *Training.*

a. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

- (1) The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;
- (2) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;
- (3) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and
- (4) The appropriate response to security alarms.

b. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations

involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

c. Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(1) Review of the training requirements of rule 641—37.43(136C) and any changes made to the security program since the last training;

(2) Reports on any relevant security issues, problems, and lessons learned;

(3) Relevant results of agency inspections; and

(4) Relevant results of the licensee's program review and testing and maintenance.

d. The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

37.43(4) Protection of information.

a. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

b. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

c. Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

(1) Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

(2) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in 37.25(1).

d. Licensees need not subject the following individuals to the background investigation elements for protection of information:

(1) The categories of individuals listed in rule 641—37.29(136C); or

(2) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 37.25(1), has been provided by the security service provider.

e. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

f. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

g. When the security plan is not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

h. The licensee shall retain as a record for three years after the document is no longer needed:

- (1) A copy of the information protection procedures; and
- (2) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—37.44 Reserved.

641—37.45(136C) LLEA coordination.

37.45(1) A licensee subject to these rules shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

- a.* A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with these rules; and
- b.* A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

37.45(2) The licensee shall notify the agency within three business days if:

- a.* The LLEA has not responded to the request for coordination within 60 days of the coordination request; or
- b.* The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

37.45(3) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three years.

37.45(4) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.46 Reserved.

641—37.47(136C) Security zones.

37.47(1) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

37.47(2) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

37.47(3) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

- a.* Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or
- b.* Direct control of the security zone by approved individuals at all times; or
- c.* A combination of continuous physical barriers and direct control.

37.47(4) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

37.47(5) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.48 Reserved.

641—37.49(136C) Monitoring, detection, and assessment.

37.49(1) Monitoring and detection.

a. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into their security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

b. Monitoring and detection must be performed by:

(1) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(2) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(3) A monitored video surveillance system; or

(4) Direct visual surveillance by approved individuals located within the security zone; or

(5) Direct visual surveillance by a licensee-designated individual located outside the security zone.

c. A licensee subject to these rules shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(1) For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

1. Electronic sensors linked to an alarm; or

2. Continuous monitored video surveillance; or

3. Direct visual surveillance.

(2) For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

37.49(2) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

37.49(3) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

a. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

b. Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

37.49(4) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.50 Reserved.

641—37.51(136C) Maintenance and testing.

37.51(1) Each licensee subject to these rules shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in

operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this chapter must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

37.51(2) The licensee shall maintain records on the maintenance and testing activities for three years.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.52 Reserved.

641—37.53(136C) Requirements for mobile devices. Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

37.53(1) Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

37.53(2) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.54 Reserved.

641—37.55(136C) Security program review.

37.55(1) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of these rules and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

37.55(2) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

37.55(3) The licensee shall maintain the review documentation for three years.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.56 Reserved.

641—37.57(136C) Reporting of events.

37.57(1) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays). In no case shall the notification to the agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

37.57(2) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays).

37.57(3) The initial telephonic notification required by 37.57(1) must be followed within a period of 30 days by a written report submitted to the agency. The report must include sufficient information for

agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.58 to 37.70 Reserved.

PHYSICAL PROTECTION IN TRANSIT

641—37.71(136C) Additional requirements for transfer of category 1 and category 2 quantities of radioactive material. A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the agency, the Nuclear Regulatory Commission or an agreement state shall meet the license verification provisions listed in this rule instead of those listed in 641—subrule 39.4(41):

37.71(1) Any licensee transferring category 1 quantities of radioactive material to a licensee of the agency, the Nuclear Regulatory Commission or an agreement state, prior to conducting such transfer, shall verify with the agency, the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

37.71(2) Any licensee transferring category 2 quantities of radioactive material to a licensee of the agency, the Nuclear Regulatory Commission or an agreement state, prior to conducting such transfer, shall verify with the agency, the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

37.71(3) In an emergency where the licensee cannot reach the agency, or the license-issuing authority and the license verification system are nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date and, for a category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by contacting the agency or by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

37.71(4) The transferor shall keep a copy of the verification documentation as a record for three years.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.72 Reserved.

641—37.73(136C) Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit. The shipping licensee shall be responsible for meeting the requirements of this chapter unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this chapter.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.74 Reserved.

641—37.75(136C) Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.

37.75(1) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

- a. Preplan and coordinate shipment arrival and departure times with the receiving licensee;
- b. Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to:
 - (1) Discuss the state's intention to provide law enforcement escorts; and
 - (2) Identify safe havens; and
- c. Document the preplanning and coordination activities.

37.75(2) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

37.75(3) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

37.75(4) Each licensee who transports or plans to transport a shipment of a category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 37.75(2) shall promptly notify the receiving licensee of the new no-later-than arrival time.

37.75(5) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three years.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.76 Reserved.

641—37.77(136C) Advance notification of shipment of category 1 quantities of radioactive material.

37.77(1) As specified in 37.77(1) "a" and "b," each licensee shall provide advance notification to the NRC and the governor of a state, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. *Procedures for submitting advance notification.*

(1) The notification must be made to the NRC and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's website at scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to (301)816-5151.

(2) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail must reach the NRC at least four days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. *Information to be furnished in advance notification of shipment.* Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

- (1) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;
- (2) The license numbers of the shipper and receiver;

- (3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;
- (4) The point of origin of the shipment and the estimated time and date that shipment will commence;
- (5) The estimated time and date that the shipment is expected to enter each state along the route;
- (6) The estimated time and date of arrival of the shipment at the destination; and
- (7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) A licensee shall promptly notify the governor of the state or the governor's designee of any changes to the information provided in accordance with 37.77(1) "b" and 37.77(1) "c" (1). The licensee shall also immediately notify the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, of any such changes.

d. Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified and to the NRC's Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

f. Protection of information. State officials, state employees, and other individuals, whether or not licensees of the commission or an agreement state, who receive schedule information of the kind specified in 37.77(1) "b" shall protect that information against unauthorized disclosure as specified in 37.43(4).

[ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—37.78 Reserved.

641—37.79(136C) Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.

37.79(1) Shipments by road.

a. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(1) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, seven days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(2) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(3) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include,

but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(4) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour-duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(5) Develop written normal and contingency procedures to address:

1. Notifications to the communication center and law enforcement agencies;

2. Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

3. Loss of communications; and

4. Responses to an actual or attempted theft or diversion of a shipment.

(6) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

b. Each licensee that transports category 2 quantities of radioactive material shall maintain constant control or surveillance, or both, during transit and have the capability for immediate communication to summon appropriate response or assistance.

c. Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(1) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control or surveillance, or both, the package tracking system must allow the shipper or transporter to identify when and where the package was last reported and when it should arrive at the next point of control.

(2) Use carriers that maintain constant control or surveillance, or both, during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

37.79(2) Shipments by rail.

a. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(1) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(2) Ensure that periodic reports to the communications center are made at preset intervals.

b. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(1) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control or surveillance, or both, the package tracking system must allow the shipper or transporter to identify when and where the package was last reported and when it should arrive at the next point of control.

(2) Use carriers that maintain constant control or surveillance, or both, during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(3) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

37.79(3) Investigations. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.80 Reserved.

641—37.81(136C) Reporting of events.

37.81(1) The shipping licensee shall notify the appropriate LLEA and the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) within 1 hour of the shipping licensee's determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by 37.79(3), the shipping licensee will provide agreed-upon updates to the agency on the status of the investigation.

37.81(2) The shipping licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) within 4 hours of the shipping licensee's determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing and the radioactive material has not been located and secured, the licensee shall immediately notify the agency.

37.81(3) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of category 1 radioactive material.

37.81(4) The shipping licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

37.81(5) The shipping licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

37.81(6) The shipping licensee shall notify the agency at (515)281-3478 (normal hours) or (515)323-4360 (after hours and holidays) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

37.81(7) The initial telephonic notification required by 37.81(1) through 37.81(4) must be followed within a period of 30 days by a written report submitted to the agency. A written report is not required for notifications on suspicious activities required by 37.81(3) and 37.81(4). The report must set forth the following information:

- a. A description of the licensed material involved, including kind, quantity, and chemical and physical form;
- b. A description of the circumstances under which the loss or theft occurred;
- c. A statement of disposition, or probable disposition, of the licensed material involved;
- d. Actions that have been taken, or will be taken, to recover the material; and
- e. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

37.81(8) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.82 to 37.100 Reserved.

RECORDS

641—37.101(136C) Form of records. Each record required by this chapter must be legible throughout the retention period specified by each agency rule. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.102 Reserved.

641—37.103(136C) Record retention. Licensees shall maintain the records that are required by this chapter for the period specified by the appropriate rule. If a retention period is not otherwise specified, these records must be retained until the agency terminates the facility's license. All records related to this chapter may be destroyed upon agency termination of the facility license.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

641—37.104 Reserved.

641—37.105(136C) Inspections.

37.105(1) Each licensee shall afford to the agency at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein the nuclear material is used, produced, or stored.

37.105(2) Each licensee shall make available to the agency for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of category 1 or category 2 quantities of radioactive material.
[ARC 1479C, IAB 6/11/14, effective 7/16/14]

CHAPTER 37—APPENDIX A

CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS

Table 1—Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

NOTE: Calculations Concerning Multiple Sources or Multiple Radionuclides. The “sum of fractions” methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this chapter.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this chapter apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation.

Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1

R_2 = total activity for radionuclide 2

R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1

AR_2 = activity threshold for radionuclide 2

AR_N = activity threshold for radionuclide n

$$\sum_1^n \left[\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$

These rules are intended to implement Iowa Code chapter 136C.

[Filed ARC 1479C (Notice ARC 1414C, IAB 4/2/14), IAB 6/11/14, effective 7/16/14]

[Filed ARC 3746C (Notice ARC 3578C, IAB 1/17/18), IAB 4/11/18, effective 5/16/18]

[Filed ARC 5059C (Notice ARC 4856C, IAB 1/15/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 38
GENERAL PROVISIONS FOR RADIATION MACHINES
AND RADIOACTIVE MATERIALS

641—38.1(136C) Purpose and scope.

38.1(1) Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

38.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

38.1(3) The provisions of Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapter 37 and Chapters 39 to 45.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1479C, IAB 6/11/14, effective 7/16/14; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—38.2(136C) Definitions. As used in these rules, these terms have the definitions set forth below and are adopted by reference and included herein for 641—Chapters 39 to 45.

“Absorbed dose” means the energy imparted by ionizing radiation per unit mass of irradiated material. It is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The units of absorbed dose are the gray (Gy) and the rad.

“Absorbed dose rate” means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

“Accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “particle accelerator” is an equivalent term.

“Accelerator-produced material” means any material made radioactive by a particle accelerator.

“Act” means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materials. (Iowa Code chapter 136C)

“Activity” means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

“Adult” means an individual 18 years of age or older.

“Agency” means the Iowa department of public health.

“Agreement state” means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689). The state of Iowa is an agreement state as of January 1, 1986.

“Airborne radioactive material” means any radioactive material dispersed in the air in the form of dusts, fumes, particles, mists, vapors, or gases.

“Airborne radioactivity area” means a room, enclosure, or area in which airborne radioactive material (composed wholly or partly of licensed material) exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

“Air kerma (K)” means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing

particles liberated by uncharged ionizing particles in air of mass dM . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

“Air-purifying respirator” means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

“Annually” means at least once every 365 days.

“As low as is reasonably achievable” (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

“Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

“Assigned protection factor (APF)” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

“Atmosphere-supplying respirator” means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

“Background radiation” means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. “Background radiation” does not include sources of radiation from radioactive materials regulated by the agency.

“Barrier” (see “Protective barrier”).

“Beam axis” means a line from the source through the centers of the X-ray fields.

“Beam-limiting device” means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X-ray field or useful beam.

“Beam monitoring system” means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

“Becquerel” (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

“Bioassay” means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, “radiobioassay” is an equivalent term.

“Bone densitometry unit” means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

“Brachytherapy” means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

“Brachytherapy source” means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

“Byproduct material” means:

1. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute “byproduct material” within this definition;

3. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity or any material that:

- Has been made radioactive by use of a particle accelerator; and
- Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

- The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat to the public health and safety or the common defense and security similar to the threat posed by a discrete source of radium-226; and

- Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

“*Cabinet radiography*” means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

“*Calendar quarter*” means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method of determining calendar quarters for purposes of these rules except at the beginning of a year.

“*Calibration*” means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

“*Carrier*” means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

“*CFR*” means Code of Federal Regulations.

“*Changeable filters*” means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

“*Collective dose*” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

“*Committed dose equivalent*” ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

“*Committed effective dose equivalent*” ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

“*Consignment*” means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

“*Consortium*” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a federal facility or a medical facility.

“*Constraint*” or “*dose constraint*” means a value above which specified licensee actions are required.

“*Controlled area*” means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

“*Critical group*” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

“*Curie*” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of $3.7E+10$ transformations per second (tps).

“*Decay-in-storage*” means the holding of radioactive material having half-lives of less than or equal to 120 days until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half-lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

“*Decommission*” means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or
2. Release of the property under restricted conditions and termination of the license.

“*Deep dose equivalent*” (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

“*Demand respirator*” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

“*Depleted uranium*” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“*Detector*” (see “Radiation detector”).

“*Diagnostic clinical procedures manual*” means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

“*Diagnostic imaging system*” means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

“*Diagnostic X-ray imaging system*” means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

“*Direct supervision*” means guidance and instruction by a qualified individual who is physically present and watching the performance of the radiological operation or procedure and in such proximity that contact can be maintained and immediate assistance can be given as required.

“*Discrete source*” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

“*Disposable respirator*” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

“*Distinguishable from background*” means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

“*Dose*” is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, “radiation dose” is an equivalent term.

“*Dose equivalent (H_T)*” means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

“*Dose limits*” means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, “limits” is an equivalent term.

“*Effective dose equivalent (H_E)*” means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

“*Embryo/fetus*” means the developing human organism from conception until the time of birth.

“*Entrance or access point*” means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

“*Exposure*” means being exposed to ionizing radiation or to radioactive material.

“*Exposure*” means the quotient of dQ by dm where “ dQ ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “ dm ” are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 641—38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as ‘exposure’ or (X), the term “exposure” has a more general meaning in these rules.

“*Exposure rate*” means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

“*External dose*” means that portion of the dose equivalent received from any source of radiation outside the body.

“*Extremity*” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. See 641—subrule 42.1(2) for definitions of “lower extremities” and “upper extremities” for purposes of certification standards.

“*Facility*” means the location, building, vehicle, or complex under one administrative control, at which radioactive material is stored or used or at which one or more radiation machines are installed, located or used.

“*FDA*” means the Food and Drug Administration.

“*Filtering facepiece (dust mask)*” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, which is not equipped with elastomeric sealing surfaces and adjustable straps.

“*Fit factor*” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

“*Fit test*” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

“*Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities*” means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

“*Generally applicable environmental radiation standards*” means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

“*Gray (Gy)*” means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (1 Gy=100 rad).

“*Half-value layer (HVL)*” means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

“*Hazardous waste*” means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

“Healing arts” means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

“Helmet” means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

“High dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate in excess of 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“High-level radioactive waste” or *“HLW”* means (1) irradiated reactor fuel; (2) liquid wastes resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and (3) solids into which such liquid wastes have been converted.

“High radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

“Highway route controlled quantity” means a quantity within a single package which exceeds:

1. 3,000 times the A_1 value of the radionuclides as specified in 49 CFR 173.435 for special form Class 7 (radioactive) material;
2. 3,000 times the A_2 value of the radionuclides as specified in 49 CFR 173.435 for normal form Class 7 (radioactive) material; or
3. 1,000 TBq (27,000 Ci), whichever is least.

“Hood” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

“Human use” means the internal or external administration of radiation or radioactive material to human beings.

“Individual” means any human being.

“Individual monitoring” means the assessment of:

1. Dose equivalent by the use of devices designed to be worn by an individual or by the use of survey data; or
2. Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. See the definition of DAC-hours in 641—Chapter 40.

“Individual monitoring devices” means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, “personnel dosimeter” and “dosimeter” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescent (OSL) devices, and personal air sampling devices.

“Industrial radiography” means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

“Inspection” means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

“Instrument traceability” means, for ionizing radiation measurements, the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be from a laboratory accredited by a program which required continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

“Interlock” means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

“Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

“Ionizing radiation.” See “Radiation.”

“Irradiation” means the exposure of a living being or matter to ionizing radiation.

“Kilovolt (kV)(kilo electron volt (keV))” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

“Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

“Leakage radiation” means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. The useful beam, and
2. Radiation produced when the exposure switch or timer is not activated.

“Lens dose equivalent (LDE)” applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

“License” means a license issued by the agency in accordance with the rules adopted by the agency.

“Licensed (or registered) material” means radioactive material received, possessed, used, transferred or disposed of under a general or specific license (or registration) issued by the agency.

“Licensed practitioner” means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, or dentistry in Iowa, or certified as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

“Licensee” means any person who is licensed by the agency in accordance with these rules and the Act.

“Licensing state” means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

“Light field” means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

“Limits.” See “Dose limits.”

“Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

“Lost or missing licensed (or registered) source of radiation” means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

“Lot tolerance percent defective” means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

“Low dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the point or surface where the dose is prescribed.

“mA” means milliamperere.

“Major processor” means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in this rule.

“Mammography” means the radiography of the breast except as defined in 641—subrule 41.6(1).

“Mammography unit” means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

“Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

“*Medical use*” means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

“*Medium dose-rate remote afterloader*” means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

“*Member of the public*” means any individual except when that individual is receiving an occupational dose.

“*Minor*” means an individual less than 18 years of age.

“*Misadministration*” means the administration of:

Radiation doses received from linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving;

Administration of external beam radiation that results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin; and either:

(1) The total dose delivered differs from the prescribed dose by 20 percent or more; or

(2) The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

(1) An administration of the wrong treatment modality.

(2) An administration to the wrong patient or human research subject.

A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

“*Monitoring (radiation monitoring, radiation protection monitoring)*” means the measurement of radiation levels, radioactive material concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

“*NARM*” means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

“*Natural radioactivity*” means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

“*Negative pressure respirator (tight fitting)*” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

“*Nuclear Regulatory Commission (NRC)*” means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

“*Occupational dose*” means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to radiation or to radioactive material from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

“*Package*” means the packaging together with its radioactive contents as presented for transport.

“*Particle accelerator*.” See “Accelerator.”

“*Patient*” means an individual or animal subjected to healing arts examination, diagnosis or treatment.

“Peak tube potential” means the maximum value of the potential difference across the X-ray tube during an exposure.

“Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

“Personnel monitoring equipment.” See “Individual monitoring devices.”

“Phantom” means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

“Pharmacist” means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

“Physician” means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

“Positive pressure respirator” means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

“Positron emission tomography (PET) radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“Powered air-purifying respirator (PAPR)” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

“Preceptor” means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a radiation safety officer, or an associate radiation safety officer.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented:

1. In a written directive; or
2. In accordance with the directions of the authorized user for procedures performed in 641—subrules 41.2(31) and 41.2(33).

“Prescribed dose” means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, particle accelerators and X-ray therapy systems, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

“Primary dose monitoring system” means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been delivered.

“Primary protective barrier” (see “Protective barrier”).

“Principal activities,” as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

“Protective barrier” means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. *“Primary protective barrier”* means the material, excluding filters, placed in the useful beam.
2. *“Secondary protective barrier”* means a barrier sufficient to attenuate the stray radiation to the required degree.

“*Public dose*” means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released under 641—subrule 41.2(27) or from voluntary participation in medical research programs.

“*Pyrophoric material*” means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C) or solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

“*Qualified expert*” means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

“*Qualitative fit test (QLFT)*” means a pass-fail fit test to assess the adequacy of respirator fit that relies on the individual’s response to the test agent.

“*Quality factor*” (Q) means the modifying factor, listed in Tables I and II of 38.4(4), that is used to derive dose equivalent from absorbed dose.

“*Quantitative fit test (QNFT)*” means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

“*Rad*” means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

“*Radiation*” means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

“*Radiation area*” means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

“*Radiation detector*” means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“*Radiation dose.*” See “Dose.”

“*Radiation machine*” means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

“*Radiation safety officer*” means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

“*Radioactive material*” means any solid, liquid, or gas which emits radiation spontaneously.

“*Radioactivity*” means the transformation of unstable atomic nuclei by the emission of radiation.

“*Radiobioassay.*” See “Bioassay.”

“*Radiographic imaging system*” means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

“*Radionuclide*” means a radioactive element or a radioactive isotope.

“*Registrant*” means any person who is registered with the agency or is legally obligated to register with the agency pursuant to these rules and the Act.

“*Registration*” means registration with the agency in accordance with the rules adopted by the agency.

“*Regulations of the U.S. Department of Transportation*” means the regulations in 49 CFR Parts 100-189.

“*Rem*” means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

“*Reportable medical event*” means the medical event:

a. In which, except for an event that results from patient intervention:

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin; and

- The total dose delivered differs from the prescribed dose by 20 percent or more;
- The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

- An administration of the wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;
- An administration of a radioactive drug containing byproduct material by the wrong route of administration;
- An administration of a dose or dosage to the wrong individual or human research subject;
- An administration of a dose or dosage delivered by the wrong mode of treatment; or
- A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

- 50 rem (0.5 Sv) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and
- 50 percent or more the expected dose from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration;

(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

1. The total source strength administered differing by 20 percent or more from the total source strength documented in the postimplantation portion of the written directive;

2. The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the postimplantation portion of the written directive; or

3. An administration that includes any of the following:

- The wrong radionuclide;
- The wrong individual or human research subject;
- Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the postimplantation portion of the written directive; or
- A leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

b. Resulting from intervention of a patient or human research subject in which administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

“*Research and development*” means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and

testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

“Residual radioactivity” means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

“Restricted area” means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

“Roentgen” means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see “Exposure” and 38.4(4)).

“Scattered radiation” means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

“Sealed source” means radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

“Sealed Source and Device Registry” or *“SSDR”* means the national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarizes the radiation safety information for the sealed sources and devices and describes the licensing and use conditions approved for the product.

“Secondary dose monitoring system” means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

“Secondary protective barrier” (see “Protective barrier”).

“Self-contained breathing apparatus (SCBA)” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

“Shallow dose equivalent” (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

“Shutter” means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

“SI” means the abbreviation for the International System of Units.

“Sievert” means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor ($1 \text{ Sv} = 100 \text{ rem}$).

“Simulator (radiation therapy simulation system)” means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

“Site area emergency” means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons off site.

“Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

“Source” means the focal spot of the X-ray tube.

“Source material” means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

“*Source material milling*” means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

“*Source of radiation*” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

“*Source traceability*” means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology or by a laboratory which participates in continuing measurement quality assurance programs with the National Institute of Standards and Technology or other equivalent national or international program.

“*Special form radioactive material*” means radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

“*Special nuclear material*” means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the agency declares by order to be special nuclear material after the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

“*Special nuclear material in quantities not sufficient to form a critical mass*” means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

“*SSD*” means the distance between the source and the skin entrance plane of the patient (see “Target-to-skin distance (TSD)”).

“*Stray radiation*” means the sum of leakage and scattered radiation.

“*Supplied-air respirator (SAR)*” or “*airline respirator*” means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

“*Survey*” means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

“*Target-to-skin distance (TSD)*” means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source scattering foil to the surface of the irradiated object or patient.

“*Termination of irradiation*” means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“*Test*” means the process of verifying compliance with an applicable regulation.

“*These rules*” means 641—Chapters 38 to 45.

“Tight-fitting facepiece” means a respirator inlet covering that forms a complete seal with the face.

“Total effective dose equivalent” (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

“Total organ dose equivalent” (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 641—40.86(1) “f.”

“Traceable to a national standard.” See “Instrument traceability” or “Source traceability.”

“Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in the written directive.

“Tube” means an X-ray tube unless otherwise specified. See “X-ray tube.”

“Tube housing assembly” means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

“Type A quantity” means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 , for normal form radioactive material as defined in 10 CFR 71.4.

“Type B quantity” means a quantity of radioactive material greater than a Type A quantity as defined in 10 CFR 71.4.

“Unrefined and unprocessed ore” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

“Unrestricted area” means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, “uncontrolled area” is an equivalent term.

“U.S. Department of Energy” means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

“User seal check (fit check)” means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

“Very high radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual’s receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.

“Waste” means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs “2,” “3” and “4” of the definition of “byproduct material” set forth in this chapter.

“Waste handling licensees” means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

“Wedge filter” means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

“Week” means seven consecutive days starting on Sunday.

“Whole body” means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

“Worker” means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

“*Working level*” (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of $1.3E+5$ MeV of potential alpha particle energy. The short-lived radon daughters are—for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

“*Working level month*” (WLM) means an exposure to 1 working level for 170 hours—2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

“*Written directive*” means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or by an individual qualified by training and experience to conduct particle accelerator therapy or radiation for X-ray therapy, as specified in 641—subrule 41.2(87).

“*X-radiation*” means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high vacuum.

“*X-ray tube*” means any electron tube which is designed to be used primarily for the production of X-rays.

“*Year*” means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—38.3(136C) Exemptions from the regulatory requirements.

38.3(1) *General provision.* The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in 641—Chapters 38 to 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Application for exemptions or exceptions should be made in accordance with 641—Chapter 178.

38.3(2) *Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.*

a. Except to the extent that NRC facilities or activities of the types subject to licensing pursuant to the Energy Reorganization Act of 1974 are involved, any prime contractor of the NRC is exempt from the license requirements of these rules and from the regulations of these rules to the extent that such contractor, under the contractor’s prime contract with the NRC, manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for:

(1) The performance of work for a department at the United States government-owned or government-controlled site, including the transportation of byproduct material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(2) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(3) The use or operation of nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

b. In addition to the foregoing exemptions and subject to the requirement for licensing of NRC facilities and activities pursuant to the requirements of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the NRC is exempt from the requirements for a license set forth in the Act and from the regulations in these rules to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under the contractor’s or subcontractor’s prime contract or subcontract when the NRC determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

c. Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from these rules to the extent that they transport or store radioactive material in the regular course of carriage for another or of storage incident thereto.

641—38.4(136C) General regulatory requirements.

38.4(1) Records.

a. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

b. Electronic records.

(1) A record or signature shall not be denied legal effect or enforceability solely because it is in electronic form.

(2) A contract shall not be denied legal effect or enforceability solely because an electronic record was used in its formation.

(3) If a rule requires a record to be in writing, an electronic record shall satisfy the rule.

(4) If a rule requires a signature, an electronic signature shall satisfy the rule.

38.4(2) Inspections.

a. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

38.4(3) Tests. Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

a. Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

38.4(4) Units of exposure and dose.

a. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent (see footnote "1")
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

1. Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

b. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 38.4(4) "*a.*" 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the

fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE
EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² Sv ⁻¹)
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

^aValue of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

^bMonoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

38.4(5) Reserved.

38.4(6) Additional requirements. The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

641—38.5 Reserved.

641—38.6(136C) Prohibited uses. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used. Radiation from radiation-emitting machines or radioactive materials shall not be used on humans for nonmedical purposes except as approved by the agency for security-related purposes.

[ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—38.7(136C) Communications.

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, Des Moines, Iowa 50319.

38.7(2) Drafts of proposed regulations released to the department from the federal government which constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination. Therefore, pursuant to Iowa Code section 22.9, the department waives the provision of Iowa Code section 22.2 as it applies to these proposed draft regulations.

641—38.8(136C) Fees.

38.8(1) Radiation machines.

a. Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a nonrefundable fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually by credit card or by check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	\$120	\$3,000
2. Osteopathy	\$120	\$3,000
3. Chiropractic	\$120	\$3,000
4. Dentistry	\$60	\$1,550
5. Podiatry	\$75	\$2,000
6. Veterinary Medicine	\$60	—
7. (Industrial/Nonmedical Use)	\$100	—
8. Food Sterilization	\$500	—
9. Accelerators and Electronic Brachytherapy Units	\$275	—
10. Electron Microscope	\$40	—
11. Bone Densitometry	\$55	—

Fees for radiation machines not listed in the above schedule shall not be less than \$120 per unit/tube.

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

1. \$1,575 for the first unit and, if the facility has additional units at the address of the first unit, a fee of \$375 for each additional unit; or

2. \$1,575 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or

3. Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria; or

4. \$675 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances; or

5. \$1,575 for each stereotactic breast biopsy unit.

(2) Mammography interpretation fees of \$100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.

(3) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of \$900 for the first unit and \$225 for each additional unit.

(4) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of \$450 for the first unit and \$130 for each additional unit.

c. Each person who is engaged in the business of installing or offering to furnish radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or service in the state shall apply for registration of such service with the agency prior to furnishing or offering to furnish any such service. Application shall be on a form provided by the department and include an annual nonrefundable fee of \$200.

d. Each person engaged in providing health physics services in mammography in Iowa who meets the requirements of 641—paragraph 41.6(3) “c” and is deemed qualified by this agency must submit a \$100 annual listing fee to this agency.

e. All mammography facilities providing services in Iowa must submit a \$150 annual authorization certification fee.

f. All Iowa-accredited facilities providing mammography services in Iowa must submit a \$200 accreditation fee for initial accreditation and each reaccreditation.

38.8(2) Radioactive material fee schedule. Fees associated with the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31 and 10 CFR 171.16. The following fee schedule shall apply.

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	\$5,400	1	\$14,600
(8.A.)	03710	CD	Civil Defense	\$2,500	5	\$2,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	\$3,200	5	\$2,600
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	\$3,100	1	\$8,000
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	\$3,400	5	\$2,000
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	\$3,400	5	\$2,000
(3.P.)	02410	IVL	<i>In-Vitro</i> Testing Laboratory	\$3,400	5	\$2,000
(7.C.)	02230	HDR	High Dose Rate Afterloader	\$5,500	1	\$5,100
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	\$5,500	3	\$4,000
(7.C.)	02121	M2	Medical – Diagnostic Only	\$5,500	4	\$3,600
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	\$5,500	2	\$4,500
(3.S.)	03210	PET	Accelerator-Produced RAM	\$7,500	1	\$5,375
(3.C.)	02500	NP	Nuclear Pharmacy	\$5,100	1	\$7,700
(7.C.)	02231	NV1	Nuclear Medical Van	\$4,140	2	\$4,000
(7.C.)	22160	PMM	Pacemaker – Byproduct and/or SNM	\$2,600	R	Note 5
(3.M.)	03620	RD2	Research & Development – Other	\$4,375	3	\$4,000

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	\$2,600	3	\$4,000
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	\$2,600	5	\$3,750
(3.P.)	03221	CAL	Calibration and W/L Tests	\$2,275	5	\$3,900
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	\$2,275	5	\$1,860
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	\$3,250	3	\$3,900
(3.B.)	03214	MD	Manufacturing/Distribution	\$3,500	3	\$3,980

NOTES:

1. Reciprocity fee is \$1,800 annually (180 days).
2. Inspection priorities are based on NRC inspection manual chapter 2800. Priority “R” is a remote contact and is not considered an inspection.
3. License amendment fee for all categories is \$600.
4. Annual fees are due no later than September 1 of each year. A 10 percent late charge will be assessed per month for late payments. Licensees with more than two authorized locations of use will be charged an additional 10 percent of the annual fee per location.
5. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the agency.
6. General license registration fee is \$700 annually on registration anniversary.

38.8(3) Industrial radiography testing and certification.

a. A nonrefundable fee of \$275 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

b. A nonrefundable fee of \$120 shall be submitted with each application, not associated with an agency-administered industrial radiography examination, for a trainee or trainer card issued to a radiographer’s assistant or an industrial radiographer.

38.8(4) Owner-assessed expenses. In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the actual expenses incurred by the agency.

38.8(5) Environmental surveillance fee. A fee may be levied against any licensee, registrant, corporation, company, business, or individual for environmental surveillance activities which are necessary to assess the radiological impact of activities conducted by the licensee, registrant, corporation, company, business, or individual. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

38.8(6) Reserved.

38.8(7) Returned check and late fees. Persons who fail to pay required fees to the agency are subject to the following penalties:

a. \$25 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. \$25 for each month for failure to pay any fee administered by this agency starting 30 days after the due date of the original notice. This fee is added to the unpaid fee.

38.8(8) Reciprocity. Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out-of-state person to operate for a total of 180 days during the 365-day reciprocity period starting the date the fee is received by the agency.

a. Radiation machines. Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$500.

b. Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in the radioactive materials fee schedule available through the agency for each 365-day reciprocity period.

38.8(9) and **38.8(10)** Reserved.

38.8(11) *Radioactive material transport fee schedule.*

a. All shippers shall pay the following fee(s) unless the department obtains sufficient funding from another source, which may include but is not limited to a federal agency or a contract with a shipper.

(1) \$1800 per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or highway route controlled quantity of radioactive materials or any material shipped in accordance with rule 641—37.77(136C) traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of \$20 per mile for every mile over 250 miles traveled.

(2) \$1300 for the first cask and \$125 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste, transuranic waste, or any material shipped in accordance with rule 641—37.77(136C) traversing the state or any portion thereof.

(3) \$175 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low-level radioactive waste or shipped to a storage site to be held for future disposal.

b. All fees must be paid by the shipper prior to shipment. Shippers must request an application for a permit to ship radioactive material from the Iowa Department of Transportation, Office of Motor Carrier Services. Assistance may be obtained by calling the Bureau of Radiological Health at (515)281-3478. Other methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

c. All fees received pursuant to this subrule shall be used for purposes related to transporting radioactive material, including enforcement and planning, developing, and maintaining a capability for emergency response.

38.8(12) *Fee waiver.* Any fee may be waived in exchange for services (low-level waste disposal, radiation detection instrument calibration, instrument repair, sample analysis, etc.) provided to the agency. The waiver may only occur as a result of a 28E agreement or memorandum of understanding between the parties.

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641—38.9(136C) Administrative enforcement actions.

38.9(1) *Scope.*

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term “regulated entity” as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. “Authorization” means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation-producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4.

38.9(2) Notice of violation.

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

- (1) Corrective steps which have been taken by the regulated entity and the results achieved;
- (2) Corrective action which will be taken to prevent recurrence; and
- (3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

c. Violations are categorized according to five levels of severity, which are:

- (1) Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.
- (2) Severity Level III: Violations are cause for significant concern.
- (3) Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.
- (4) Severity Level V: Violations are of minor safety or environmental concern.

d. A group of violations may be evaluated in the aggregate and assigned a single higher severity level if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.

e. The severity level of a violation may be increased if the violation can be considered a repetitive violation. The term “repetitive violation” or “similar violation” means a violation that reasonably could have been prevented by a regulated entity’s corrective action for a previous violation normally occurring within the past two years of the inspection at issue or the period within the last two inspections, whichever is longer.

f. The severity level of a violation may be increased if the violation involves casual disregard of requirements, deception, or other indications of willfulness. The term “willfulness” is that characteristic of violations ranging from deliberate intent to violate or falsify to intentional disregard for regulatory requirements.

38.9(3) Orders.

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

- (1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;
- (2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;
- (3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;
- (4) Specify the issues for hearing; and
- (5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph “d” of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) Settlement and compromise. At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty.

38.9(5) Demand for information.

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity’s answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5) “a”(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3) “d.”

38.9(6) Civil penalties.

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6) "b," an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6) "a."

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6) "c" or "f," or the expiration of the time for requesting a hearing described in 38.9(6) "d," the agency may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) Requests for action under this rule.

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7) "b."

b. Within a reasonable time after a request pursuant to 38.9(7) "a" has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c. (1) The bureau chief's decisions under this rule will be filed and within 25 days after the date of the bureau chief's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief's decision under this rule will be entertained by the agency.

38.9(8) Impounding. The agency may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of Iowa Code chapter 136C, or any rules, license or registration conditions, or orders issued by this agency.

a. If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give to either the owner or the possessor of the source of radiation written notice of the intention to impound the source of radiation.

(1) Either the owner or the possessor shall have 20 days from the date of personal service of certified mailing to request a hearing, except in the case where the regulated entity has consented in writing to the impoundment.

(2) If a hearing is requested, the agency will issue an order designating the time and place of hearing.

b. At the agency's direction, the impounded sources of radiation may be disposed of by:

(1) Returning the source of radiation to a properly licensed or registered owner that did not cause the emergency;

(2) Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or

(3) Selling, destroying, or disposing of the source of radiation in another manner within the agency's discretion.

[ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—38.10(136C) Deliberate misconduct.

38.10(1) Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this rule, may not:

a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

b. Deliberately submit to the agency, a licensee, registrant, applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

38.10(2) A person who violates paragraph 38.10(1) "a" or "b" may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

38.10(3) For the purposes of paragraph 38.10(1) "a," deliberate misconduct by a person means an intentional act or omission that the person knows:

a. Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the agency; or

b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

These rules are intended to implement Iowa Code chapter 136C.

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⁰ Two or more ARCs

¹ Effective date of 38.8(11) delayed 70 days from May 9, 2001, by the Administrative Rules Review Committee at its meeting held May 4, 2001.
 At its meeting held July 10, 2001, the Committee delayed the effective date until adjournment of the 2002 Session of the General Assembly.

CHAPTER 39
REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE
MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641—39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

39.1(4) In addition to the requirements of this chapter, all registrants are subject to the requirements of 641—Chapters 38 and 40. Furthermore, registrants engaged in healing arts are subject to the requirements of 641—Chapters 41 and 42; registrants engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45.

39.1(5) In areas under exclusive federal jurisdiction, nothing in these rules applies to the extent that persons are subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) or other federal agencies.

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641—39.2(136C) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 38 may also apply to this chapter.

641—39.3(136C) Requirements for registration of X-ray and other electronic machines that produce radiation.

39.3(1) Exemptions.

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 μ Sv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) Application for registration of radiation machine facilities. Each person having a radiation machine facility shall:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a storage area located in Iowa where records of equipment maintenance and quality assurance, personnel monitoring, and personnel certification must be kept for review during an inspection. The records may be stored on a vehicle, if appropriate. An Iowa mailing address is not required. Application for registration shall be completed on forms furnished by the agency, shall contain all information required by the agency as indicated on the forms and accompanying instructions, and shall include the appropriate fee from 641—38.8(136C).

b. Designate on the application form an individual to be responsible for radiation protection.

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3) “*d*” to the registrant’s radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).

39.3(3) Application for registration of servicing and services.

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services

in this state shall apply for registration of such services with the agency prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions and include the fee required in 641—paragraph 38.8(1)“*c.*”

c. Each person applying for registration under this chapter shall specify:

- (1) That the person has read and understands the requirements of these rules;
- (2) The services for which the person is applying for registration;
- (3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;
- (4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and
- (5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

d. For the purpose of 39.3(3), services may include but shall not be limited to:

- (1) Installation and servicing of radiation machines and associated radiation machine components;
- (2) Calibration of radiation machines or radiation measurement instruments or devices;
- (3) Radiation protection or health physics consultations or surveys; and
- (4) Processor or processor servicing, or both.
- (5) Calibration and compliance surveys of external beam radiation therapy units.

e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

f. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapters 38 through 45.

g. Radiation therapy physicists providing services for therapeutic radiation machines must provide proof that the training requirements of 641—subrule 41.3(6) have been met.

39.3(4) Issuance of notice of registration.

a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.

b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant’s receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

39.3(5) Expiration of notice of registration. Except as provided by 39.3(6)“*b.*,” each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) Renewal of notice of registration.

a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).

b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.

39.3(7) Report of changes. The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate.

39.3(8) Approval not implied. No person, in any advertisement, shall refer to the fact that the person or the person’s facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall state or imply that any activity under such registration has been approved by the agency.

39.3(9) Assembler and transfer obligation.

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency in writing within 15 days of:

- (1) The name and address of persons who have received these machines;
- (2) The manufacturer, model, and serial number of each radiation machine transferred; and

(3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) Reciprocity—out-of-state radiation machines.

a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least three working days before such machine is to be used in the state. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and
- (4) States in which this machine is registered.

b. If, for a specific case, the three-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

c. The person referred to in 39.3(10)“a” shall:

- (1) Comply with all applicable rules of the agency;
- (2) Supply the agency with such other information as the agency may reasonably request; and
- (3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365-day reciprocity period. The 365-day reciprocity period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant's responsibility to ensure the 180-day limit is not exceeded during the 365-day reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365-day reciprocity period.

[ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) Additional requirements.

a. In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.

b. An Iowa radioactive materials license requires that the person have a permanent storage area in Iowa where records are maintained pertaining to licensed activities, equipment maintenance and quality assurance, personnel monitoring, and personnel certification and where material can be stored. The records may be stored on a van, if appropriate. The storage area must be accessible during inspections. An Iowa mailing address is not required.

39.4(2) Source material.

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from the requirements for a license set forth in this chapter and from the rules in this chapter and 641—Chapter 40 to the extent that such person receives, possesses, uses, or transfers:

- (1) Any quantities of thorium contained in:
 1. Incandescent gas mantles,
 2. Vacuum tubes,
 3. Welding rods,
 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
 5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,
 6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or
 7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.
- (2) Source material contained in the following products:
 1. Glazed ceramic tableware manufactured before November 5, 2014, provided that the glaze contains not more than 20 percent by weight source material,
 2. Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before November 5, 2014, 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,
 3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
 4. Piezoelectric ceramic containing not more than 2 percent by weight source material.
- (3) Photographic film, negatives, and prints containing uranium or thorium.
- (4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
- (5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
 1. Reserved.
 2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"
 3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," and
 4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.
- (6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
 1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and
 2. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).
- (7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before November 5, 2014, 30 percent by weight of thorium; and that this exemption does not authorize either:
 1. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or

2. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Reserved.

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

2. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

d. The exemptions in 39.4(2) do not authorize the manufacture of any of the products described.

e. The requirements specified in 39.4(2) “c”(5) “2” and “3” need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, “CAUTION—RADIOACTIVE MATERIAL—URANIUM,” as previously required by the rules.

f. No person may initially transfer for sale or distribution a product containing source material to persons exempt under these rules, or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(1) Persons initially transferring for sale or distributing source material in products covered by the exemptions in these rules before November 5, 2014, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(2) Persons authorized to manufacture, process, or produce these materials or products containing source material by the agency, an agreement state, or the Nuclear Regulatory Commission, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 641—Chapter 40 and 39.4(25) “a” and “b.”

39.4(3) Radioactive material other than source material.

a. Exempt concentrations.

(1) Except as provided in 39.4(3) “a”(2), any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3) “a”(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any agreement state, except in accordance with a specific license issued pursuant to 10 CFR 32.11.

(3) An exemption is granted to persons who receive, possess, use, process, transfer, distribute, and dispose of materials containing or contaminated at concentrations less than 20 picocuries per gram of radium.

(4) This rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(5) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license and from these rules to the extent that the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of the requirements in Appendix A of this chapter and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

b. Exempt quantities.

(1) Except as provided in 39.4(3) “b”(3), (4), and (5), any person is exempt from the requirements for a license and from these rules to the extent that such person receives, possesses, uses, transfers, owns,

or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under a general license is exempt from the requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material.

(3) This paragraph (39.4(3) "b") does not authorize for purposes of commercial distribution the production, packaging, repackaging or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32, which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3) "b" or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this chapter, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

c. Exempt items.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

- 25 millicuries (925 MBq) of tritium per timepiece;
- 5 millicuries (185 MBq) of tritium per hand;
- 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;
- 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;
- 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
- One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

2. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

- For wrist watches, 0.1 millirad (1 μ Gy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1 μ Gy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2 μ Gy) per hour at 10 centimeters from any surface.

3. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

4. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

5. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

- 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
- 1 microcurie (37 kBq) of cobalt-60;
- 5 microcuries (185 kBq) of nickel-63;
- 30 microcuries (1.11 MBq) of krypton-85;
- 5 microcuries (185 kBq) of cesium-137; and
- 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 μ Gy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. For purposes of 39.4(3)“c”(1)“5,” the term “electron tubes” includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

6. Ionizing radiation measuring instruments, for purposes of internal calibration or standardization, containing one or more sources of radioactive material, provided that:

- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each device contains no more than ten exempt quantities. For purposes of this requirement, a device’s source(s) may contain either one type of or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or
- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)“c”(1)“6.”

7. Ionization chamber smoke detectors containing not more than 1 microcurie (μ Ci) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in subparagraph 39.4(3)“c”(1), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license with the Nuclear Regulatory Commission pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subparagraph 39.4(3)“c”(1).

(2) Self-luminous products containing radioactive material.

1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under these rules. Any person who desires to manufacture, process, produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use according to this paragraph shall apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. The exemption in 39.4(3)“c”(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. Radium-226. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from the requirements contained in 641—Chapters 38, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 20, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to 39.4(3)“c”(3)“1,” shall apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210.

(4) 1. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before November 5, 2014, for use under the general license that was provided in 39.4(22)“a” and equivalent regulations of an agreement state or the Nuclear Regulatory Commission and manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency.

(5) Radioactive drug: capsules containing carbon-14 urea for “in vivo” diagnostic use for humans.

1. Except as provided in paragraphs “b” and “c” of this subrule, any person is exempt from the requirements for a license set forth in this chapter and in 641—41.2(136C) provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq 1µCi carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for “in vivo” diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 641—41.2(136C).

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 39.4(20) of this rule.

4. Nothing in this subrule relieves persons from complying with applicable FDA or other federal or state requirements governing receipt, administration, and use of drugs.

(6) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under these rules. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing

byproduct material for use under these rules should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

39.4(4) to 39.4(19) Reserved.

39.4(20) *Types of licenses.* There are two types of licenses for radioactive materials: general and specific.

a. General licenses provided in this chapter are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate or registration application with the agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these rules and any limitations of the general license.

b. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

c. All licensees and registrants must submit the appropriate fee in 641—subrule 38.8(2).

39.4(21) *General licenses—source material.*

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and federal, state and local government agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of November 5, 2014, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the agency takes final action on a pending application submitted on or before November 5, 2015, for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of 39.4(21)“a”(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

b. Any person who receives, possesses, uses, or transfers source material in accordance with the general license issued in 39.4(21)“a”:

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

1. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this chapter to the extent the source material is permanently disposed. This

provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

2. In accordance with 641—40.70(136C).

(3) Is subject to the provisions in 641—38.4(136C), 641—38.9(136C), 39.4(21), 39.4(32) “a” through “d” and “f,” 39.4(41), 39.4(51), 39.4(52), 641—40.95(136C), 641—40.96(136C), and 641—40.97(136C).

(4) Reserved.

(5) Shall not export such source material except in accordance with 10 CFR Part 110.

c. Any person who receives, possesses, uses, or transfers source material in accordance with 39.4(21) “a” shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 641—40.29(136C).

d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

e. Depleted uranium in industrial products and devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 39.4(21) “e”(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 39.4(21) “e”(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 39.4(29) “m” or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3) 1. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 39.4(21) “e”(1) shall file Agency Form “Registration Certificate—Use of Depleted Uranium Under General License” with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the Agency Form “Registration Certificate—Use of Depleted Uranium Under a General License” the following information and such other information as may be required by that form:

- Name and address of the general licensee;
- A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 39.4(21) “e”(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
- Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 39.4(21) “e”(3) “1.”

2. The general licensee possessing or using depleted uranium under the general license established by 39.4(21) “e”(1) shall report in writing to the agency any changes in information furnished by the general licensee in Agency Form “Registration Certificate—Use of Depleted Uranium Under General License.” The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 39.4(21) “e”(1):

1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

2. Shall not abandon such depleted uranium;

3. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 39.4(41). In the case where the transferee receives the depleted uranium pursuant to the general license established by 39.4(21)“e”(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of Agency Form “Registration Certificate—Use of Depleted Uranium Under General License.” In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission’s or agreement state’s regulation equivalent to 39.4(21)“e”(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of the Agency Form “Registration Certificate—Use of Depleted Uranium Under General License” accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 641—Chapters 38, 39, 40, 41 and 45;

4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 39.4(21)“e”(1) is exempt from the requirements of 641—Chapter 40 with respect to the depleted uranium covered by that general license.

f. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 39.4(21)“a” is exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 641—40.29(136C) and 641—40.70(136C) to the extent necessary to meet the provisions of 39.4(21)“b”(2) and 39.4(21)“c.” However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

g. No person may initially transfer or distribute source material to persons generally licensed under 39.4(21)“a”(1) and (2), or equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a specific license issued in accordance with 39.4(39) or equivalent provisions of the Nuclear Regulatory Commission or an agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by 39.4(21)“a” before November 5, 2014, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before November 5, 2015.

39.4(22) General licenses—radioactive material other than source material. This subrule establishes general licenses for the possession and use of radioactive material and a general license for ownership of radioactive material. (Note: Different general licenses are issued in this subrule, each of which has its own specific conditions and requirements.)

a. to c. Reserved.

d. Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of 39.4(22)“d”(2), (3), and (4), radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in 39.4(22)“d”(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license by this agency issued under 39.4(29)“d”; or an equivalent specific license issued by the NRC or an agreement state or a licensing state; or an equivalent specific license issued by a state with provisions comparable to 39.4(29)“d,” which authorizes distribution of the devices.

The devices must have been received from one of the specific licensees described in 39.4(22) "d"(2) or through a transfer made under 39.4(22) "d"(3).

(3) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in 39.4(22) "d"(1):

1. Shall ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall ensure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; However,

- Devices containing only krypton need not be tested for leakage of radioactive material; and
- Devices containing only tritium or not more than 100 microcuries of other beta- or gamma-emitting material or both or 10 microcuries of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall ensure that the test required by 39.4(22) "d"(3) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment are performed:

- In accordance with the instructions provided by the labels; or
- By a person holding a specific license pursuant to 641—39.4(136C), the NRC, an agreement state or a licensing state to perform such activities;

4. Shall maintain records showing compliance with the requirements of 39.4(22) "d"(3). The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

- Each record of a test for leakage or radioactive material required by 39.4(22) "d"(3) must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

- Each record of a test of the on-off mechanism and indicator required by 39.4(22) "d"(3) must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;

- Each record that is required by 39.4(22) "d"(3) must be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

5. Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued by this agency, the NRC, an agreement state or licensing state. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by this agency. A report containing a brief description of the event and the remedial action taken, and in the case of detection of 0.005 microcurie (185 Bq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the agency within 30 days. Under these circumstances, the criteria set out in 641—40.29(136C) may be applicable, as determined by the agency on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. Shall not export the device containing radioactive material except in accordance with 10 CFR Part 110;

8. Shall transfer or dispose of the device containing radioactive material only by export as provided by 39.4(22) "d"(3) "7," by transfer to another general licensee as authorized in 39.4(22) "d"(3) "9," to a person authorized to receive the device by a specific license issued by the agency, the NRC, an agreement

state or a licensing state whose specific license authorizes the person to receive the device or which authorizes waste collection, or as otherwise approved under 39.4(22) "d"(3):

- Shall furnish a report to this agency within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address and license number of the person receiving the device (license number not applicable if device is exported); and the date of the transfer;

- Shall obtain written agency approval before transferring the device to any other specific licensee not specifically identified in 39.4(22) "d"; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

- Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

- Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 39.4(22) "d"(3)"1") so that the device is labeled in compliance with 641—40.63(136C) of these rules; however the manufacturer, model number, and serial number must be retained;

- Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak-testing procedures); and

- Reports the transfer under 39.4(22) "d"(3)"8" of this chapter.

9. Shall transfer the device to another general licensee only if:

- The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of these rules and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to this agency the manufacturer's (or initial transferor's) name; the model number and the serial number of the device transferred; the transferee's name and mailing address for the location of use; and the name, title, and telephone number of the responsible individual identified by the transferee in accordance with 39.4(22) "d"(3)"12" to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

- The device is held in storage, by an intermediate person, in the original shipping container at its intended location of use prior to initial use by a general licensee;

10. Shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40;

11. Shall respond to written requests from this agency to provide information relating to the general license within 30 calendar days of the date of the request, or other item specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the agency and providing written justification as to why it cannot comply;

12. Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

13. Shall register as follows:

- Shall register devices as approved in the Sealed Source and Device Registry. Each address for a location of use, as described in 39.4(22) "d"(3)"13," represents a separate general licensee and requires a separate registration and fee;

- If in possession of devices meeting the criteria of 39.4(22) "d"(3)"13," shall register these devices annually with the agency and shall pay the fee required in 641—paragraph 38.8(2) "c." Registration must be done by verifying, correcting, and adding to the information provided in a request for registration received from the agency. The registration information must be submitted 30 days from the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of 39.4(22) "d"(3)"13" is subject to the bankruptcy notification requirement of 39.4(32) "e";

- In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the agency:

- Name and mailing address of the general licensee;

- Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);

- Name, title, and telephone number of the responsible person designated as a representative of the general licensee;

- Address or location at which the device(s) is both used and stored. For portable devices, the address of the primary place of storage;

- Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and check of label information;

- Certification by the responsible representative of the general licensee that the licensee is aware of the requirements of the general license.

- Persons generally licensed by this agency under 39.4(22) “d”(3)“13” or an agreement state are not subject to registration requirements of 39.4(22) “d”(3)“13” if the devices are used in areas subject to this agency’s jurisdiction for a period of less than 180 days in any calendar year. The agency will not request registration information from such licensees;

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device’s primary place of storage; and

15. May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by 39.4(22) “d” need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in 39.4(22) “d”(1) does not authorize the manufacture or import of devices containing radioactive material.

(5) A general license to install devices generally licensed in 39.4(22) “d.” Any person who holds a specific license issued by an agreement state authorizing the holder to manufacture, install, or service a device described in 39.4(22) “d” within such agreement state is hereby granted a general license to install and service such device in any non-agreement state and a general license to install and service such device in offshore waters, as defined in 641—45.1(136C), provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with the applicable provision of the specific license issued to such person by the agreement state, and

2. Such person ensures that any labels required to be affixed to the device under regulations of the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

e. Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 39.4(22) “e”(1) are exempt from the requirements of 641—Chapter 40 except that they shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C).

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

f. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

g. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 39.4(22) “g”(4) and (5), americium-241 in the form of calibration or reference sources:

1. Any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material; and

2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the person to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 39.4(22) “g”(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 39.4(22) “g”(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in 39.4(22) “g”(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 39.4(22) “g”(1), (2), and (3) are subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;

2. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

• The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241).
(PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH
RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

OR

• The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS RADIUM-226.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

3. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to receive the source;

4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

h. Reserved.

i. General license for use of radioactive material for certain in vitro clinical or laboratory testing. The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 39.4(22) "i"(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

1. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.
2. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.
3. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
4. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
5. Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.
6. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.
7. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
8. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 39.4(22) "i"(1) until the person has filed an Agency Form "Certificate—In Vitro Testing with Radioactive Material Under General License" with the agency and received from the agency a validated copy of the form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish the following information on the form and such other information as may be required by the form:

1. Name and address of the physician, veterinarian, clinical laboratory or hospital;
2. The location of use; and
3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 39.4(22) "i"(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 39.4(22) "i"(1) shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to the general license in 39.4(22) "i"(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq).

2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22) "i"(1).

4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in 39.4(22) "i"(1)"8" as required by 641—subrule 40.70(1).

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22) "i"(1):

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29) "h" or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under 39.4(22) "i" or its equivalent, and

2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22) "i"(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 39.4(22) "i"(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in 39.4(22) "i"(1)"8" shall comply with the provisions of 641—subrule 40.70(1) and rules 641—40.95(136C) and 641—40.96(136C).

j. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 39.4(22) "j"(1):

1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.70(1);

2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrule 40.70(1), and rules 641—40.95(136C) and 641—40.96(136C).

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

k. Certain items and self-luminous products containing radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with 39.4(22) "k"(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.

1. Antiquities originally intended for use by the general public. For the purposes of this subrule, "antiquities" means products originally intended for use by the general public and distributed in the late nineteenth and early twentieth centuries including, but not limited to, radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2. Intact and non-intact timepieces containing greater than 1 microcurie (0.037 megabecquerel), and timepiece hands and dials no longer installed in timepieces.

3. Luminous items installed in air, marine, or land vehicles.

4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

5. Small radium sources containing no more than 1 microcurie (0.037 megabecquerel) of radium-226. For the purposes of this subrule, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the agency.

(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in 39.4(22) "k"(1) shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 39.4(24).

(3) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in 39.4(22) "k"(1) shall:

1. Notify the agency if there is any indication of possible damage to the product which could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken must be furnished to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa, within 30 calendar days.

2. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 641—40.77(136C) or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

3. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

4. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 39.4(24), or equivalent NRC or agreement state requirements, or as otherwise approved by the agency.

5. Respond in writing to a written request from the agency to provide information relating to the general license within 30 calendar days of the request, or other time specified in the request.

(4) The general license in 39.4(22)“k”(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

39.4(23) Reserved.

39.4(24) *Filing application for specific licenses.*

a. Applications for specific licenses shall be filed on a form prescribed by the agency and include the fee required in 641—subrule 38.8(2).

b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant’s or licensee’s behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

f. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)“f”(1)“1” of this subrule:

1. The radioactive material is physically separated so that only a portion could be involved in an accident;

2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix G due to the chemical or physical form of the material;

4. The solubility of the radioactive material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix G;

6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix G; or

7. Other factors appropriated for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)“f”(1)“2” must include the following information:

1. Facility description. A brief description of the licensee’s facility and area near the site.

2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

8. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

9. Information to be communicated. A brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub.L.No. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

g. (1) Except as provided in 39.4(24) “g”(2), (3), and (4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material as registered with a state under provisions comparable to 10 CFR 32.210; or

2. Contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured prior to November 5, 2014, that are not registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all the categories of information specified in 10 CFR 32.210(c), the application must include:

1. All available information identified in 10 CFR 32.210(c) concerning the source and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a current leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

h. An application from a medical facility or an educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in the facility’s or educational institution’s consortium authorized for medical use under 641—41.2(136C) or equivalent NRC or agreement state requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this chapter or equivalent NRC or agreement state requirements for a PET production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 39.4(29) “j”(1)“2.”

(3) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 39.4(29) “j”(2)“2.”

(4) Information identified in 39.4(29) “j”(1)“3” on the PET drugs to be noncommercially transferred to members of the facility’s consortium.

39.4(25) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;

b. The applicant’s proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public; and

d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), or 641—Chapter 45.

e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement

of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

39.4(26) *Financial assurance and record keeping for decommissioning.*

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding $1.0E^5$ times the applicable quantities set forth in Appendix F of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26) "e." The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

b. (1) Each holder of or applicant for a specific license authorizing possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in 39.4(26) "d" (or when a combination of isotopes is involved if R , as defined in 39.4(26) "a," divided by 10^{12} is greater than 1) shall submit a decommissioning funding plan as described in 39.4(26) "e."

(2) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 39.4(26) "d" shall either:

1. Submit a decommissioning funding plan as described in 39.4(26) "e"; or
2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26) "d" using one of the methods described in 39.4(26) "f." For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) "f" must be submitted before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) "f."

c. (1) Each holder of a specific license issued on or after July 1, 1993, which is of a type described in 39.4(26) "a" or "b," shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.

(2) Each holder of a specific license issued before July 1, 1993, and of a type described in 39.4(26) "a," shall submit, on or before January 1, 2007, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36) "b," shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.

(4) Any licensee who submitted an application before July 1, 2003, for renewal of license shall provide financial assurance for decommissioning in accordance with 39.4(26) "a" and "b."

(5) Waste collectors and waste processors must provide financial assurance in an amount based on a decommissioning funding plan as described in 39.4(26) "e." The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license,

and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee’s facility at any time, in addition to the cost to remediate the licensee’s site to meet the license termination criteria of 641—Chapters 39 and 40.

(6) If, in surveys made under 641—subrule 40.36(1), residual radioactivity in the facility and the environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 641—40.29(136C) criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10 ⁴ but less than or equal to 10 ⁵ times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26) “a,” divided by 10 ⁴ is greater than 1, but R divided by 10 ⁵ is less than or equal to 1.)	1,125,000
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Greater than 10 ³ but less than or equal to 10 ⁴ times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26) “a,” divided by 10 ³ is greater than 1, but R divided by 10 ⁴ is less than or equal to 1.)	225,000
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Greater than 10 ¹⁰ but less than or equal to 10 ¹² times the applicable quantities of Appendix F or 641—Chapter 40 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 39.4(26) “a,” divided by 10 ¹⁰ is greater than 1, but R divided by 10 ¹² is less than or equal to 1.)	113,000
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Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan

e. (1) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. A detailed cost estimate for decommissioning, in an amount reflecting:
 - The cost of an independent contractor to perform all decommissioning activities;
 - The cost of meeting the 641—40.29(136C) criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 641—40.30(136C), the cost estimate may be based on meeting the 641—40.30(136C) criteria;
 - The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
 - An adequate contingency factor;
2. Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);
3. A description of the method of assuring funds for decommissioning from 39.4(26) “f,” including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;
4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and
5. A signed original of the financial instrument obtained to satisfy the requirements of 39.4(26) “f” (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be

done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;
2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;
5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. Onsite disposal; and
8. Use of a settling pond.

f. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix H of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I of this chapter. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J of this chapter. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of paragraph 39.4(26) "f" or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

1. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in effect until the agency has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26) "f"(2).

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 39.4(26) "d," and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is released for unrestricted use. Before licensed activities are transferred or assigned to another licensee, the licensee shall transfer all records described in this subrule to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. All areas designated as restricted areas as defined under 641—38.2(136C);
2. All areas outside of restricted areas that require documentation under 641—39.4(26) "g"(1);
3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 641—40.88(136C); and
4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 641—40.71(136C).

39.4(27) *Special requirements for issuance of certain specific licenses for radioactive material.*

a. to d. Reserved.

e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if the application contains:

- (1) A schedule or description of the program for training radiographic personnel which specifies:
 1. Initial training,
 2. Periodic training,

3. On-the-job training, and
4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;
 - (2) Written operating and emergency procedures, including all items listed in Appendix D of 641—Chapter 45;
 - (3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;
 - (4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any of the following applies to the location:
 1. Non-wireless telephone service is established by the licensee;
 2. Industrial radiographic services are advertised for or from the location;
 3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;
 - (5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;
 - (6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 641—subrule 45.1(8) and 641—Chapter 45, Appendix A); and
 - (7) If a license application includes underwater radiography, a description of:
 1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
 2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
 3. Methods for gas-tight encapsulation of equipment;
 - (8) If a license application includes offshore platform or lay-barge radiography, a description of:
 1. Transport procedures for radioactive material to be used in industrial radiographic operations;
 2. Storage facilities for radioactive material; and
 3. Methods for restricting access to radiation areas.

39.4(28) *Special requirements for specific licenses of broad scope.* This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

a. The different types of broad scope licenses are set forth below:

(1) A “Type A specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A “Type B specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A “Type C specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

3. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;

- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

- Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 39.4(28) “b”(3)“3” prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

2. The establishment of appropriate administrative procedures to ensure:

- Control of procurement and use of radioactive material;

- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

- Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 39.4(28) “c”(2)“2” prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 39.4(28) shall not:

- 1. Conduct tracer studies in the environment involving direct release of radioactive material;
- 2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;
- 3. Conduct activities for which a specific license issued by the agency under 39.4(27), 39.4(29) or 641—41.2(136C) is required; or
- 4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety committee.

(3) Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee’s radiation safety officer.

(4) Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 39.4(28)“d.”

39.4(29) Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

- a. Rescinded IAB 7/29/09, effective 9/2/09.
- b. Rescinded IAB 3/30/05, effective 5/4/05.
- c. Rescinded IAB 7/29/09, effective 9/2/09.
- d. Licensing the manufacture and distribution of devices to persons generally licensed under 39.4(22)“d.”

(1) An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22)“d” or equivalent regulations of the NRC, an agreement state, or a licensing state will be approved if:

- 1. The applicant satisfies the general requirements of 39.4(25);
- 2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - The device can be safely operated by persons not having training in radiological protection,
 - Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C); and
 - Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens
 of eye 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter 200 rems (2 Sv)

Other organs. 50 rems (500 mSv)

3. Each device bears a durable, legible, clearly visible label or labels approved by the agency, NRC, or agreement state or licensing state, which contains in a clearly identified and separate statement:

- Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;
- The requirement, or lack of requirement, for leak testing, or for testing any “on-off” mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
- The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, (devices licensed prior to January 19, 1975, may bear labels authorized by the rules in effect on January 1, 1975)(the model, serial number, and name of the manufacturer or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device) are subject to a general license or the equivalent and the chapter of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

 Name of manufacturer or initial transferor

4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words “Caution—Radioactive Material,” the radiation symbol described in 641—subrule 40.60(1), and the name of the manufacturer or initial distributor;

5. Each device meeting the criteria of 39.4(22) “d”(3)“13” bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “Caution—Radioactive Material,” and, if practicable, the radiation symbol described in 641—subrule 40.60(1); and

6. The device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the “on-off” mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the “on-off” mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:

1. Primary containment or source capsule;
2. Protection of primary containment;
3. Method of sealing containment;
4. Containment construction materials;
5. Form of contained radioactive material;
6. Maximum temperature withstood during prototype tests;
7. Maximum pressure withstood during prototype tests;
8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and
10. Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 39.4(22)“d,” or under equivalent regulations of the NRC, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the “on-off” mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in 641—40.15(136C).

(4) Information to be provided before transfer.

1. If a device containing radioactive material is to be transferred for use under the general license contained in 39.4(22)“d,” each person that is licensed under 39.4(22)“d” shall provide the information specified to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the general license contained in 39.4(22), or if 39.4(22)“d”(3)“2,” “3,” or “4” or 39.4(22)“d”(3)“13” does not apply to the particular device, those paragraphs may be omitted;
- A copy of 39.4(20), 39.4(52), 641—40.95(136C), and 641—40.96(136C);
- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs of disposal; and
- An indication that it is the policy of the NRC and this agency to issue high civil penalties for improper disposal.

2. If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, each person that is licensed under 39.4(29)“d” shall provide the information specified in this paragraph to each person to whom a device is to be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

- A copy of the NRC or agreement state’s rules equivalent to 39.4(29)“d.” If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the agreement state’s regulations, it shall be accompanied by a note explaining that use of the device is regulated by the agreement state; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

- A list of the services that can only be performed by a specific licensee;
- Information on acceptable disposal options including estimated costs of disposal; and
- The name or title, address, and telephone number of the contact at the agreement state regulatory agency from which additional information may be obtained.

3. An alternative approach to informing customers may be proposed by the licensee for approval by the agency.

4. Each device that is transferred after February 19, 2002, must meet the labeling requirements in 39.4(29)“d.”

5. If a notification of bankruptcy has been made or the license is to be terminated, each person licensed under 39.4(29)“d” shall provide, upon request, to the NRC and to any appropriate agreement state, records of final disposition.

(5) Transfer reports and records. Each person licensed under 39.4(29)“d” to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

1. The person shall report all transfers of devices to persons for use under the general license in 39.4(29)“d” and all receipts of devices from persons licensed under 39.4(29)“d” to the NRC, this agency, or another agreement state. The report must be submitted on a quarterly basis in a clear and

legible report containing all of the data required in this subrule. The required information for transfers to general licensees includes:

- The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

- The name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

- The date of transfer;
- The type, model number, and serial number of the device transferred; and
- The quantity and type of radioactive material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address; the type, model number, and serial number of the device received; the date of receipt; and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update the required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

7. If no transfers have been made to or from persons generally licensed under 39.4(29) "d" during the reporting period, the report must so indicate.

(6) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 39.4(29) "d." Records required in 39.4(29) "d" must be maintained for three years following the date of the recorded event.

e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 39.4(22) "e," will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25); and
- (2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR Part 32, or their equivalent.

f. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under 39.4(22) "g" will be approved if:

- (1) The applicant satisfies the general requirements of 39.4(25); and
- (2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR Part 32, or their equivalent.

g. Reserved.

h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 39.4(22) "i" will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The radioactive material is to be prepared for distribution in prepackaged units of:
 1. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
 2. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
 3. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

5. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

6. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

7. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

8. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

2. Displaying the radiation caution symbol described in 641—subrule 40.60(1) and the words, “CAUTION—RADIOACTIVE MATERIAL,” and “Not for Internal or External Use in Humans or Animals.”

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or an agreement state.

Name of manufacturer

2. Rescinded IAB 3/30/05, effective 5/4/05.

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 641—subrule 40.70(1).

i. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 to persons generally licensed under 39.4(22) “j” will be approved if the applicant satisfies the general requirements of 39.4(25) and the requirements of Sections 32.61 and 32.62 of 10 CFR Part 32, or their equivalent.

j. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 641—41.2(136C).

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. The applicant satisfies the general requirements specified in subrule 39.4(25);

2. The applicant submits evidence that the applicant is at least one of the following:

- Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

- Registered or licensed with a state agency as a drug manufacturer;

- Licensed by the Iowa board of pharmacy as a nuclear pharmacy;

- Operating as a nuclear pharmacy within a federal medical institution; or

- A positron emission tomography (PET) drug production facility registered or licensed with a state agency;

3. The applicant submits information on the radionuclide: the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

4. The applicant commits to the following labeling requirements:

- A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

- A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee as described by 39.4(29)“j”(1)“2”:

1. May prepare radioactive drugs for medical use, as defined in 641—38.2(136C), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 39.4(29)“j”(2)“2” and 39.4(29)“j”(2)“3” or an individual under the supervision of an authorized nuclear pharmacist as specified in 641—paragraph 41.2(11)“c.”

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),

- This individual meets the requirements specified in 641—subrules 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)“j”(2)“3.”

3. May designate a pharmacist (as defined in 641—subrule 41.2(2)) as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

4. Shall permit the actions authorized in 39.4(29)“j”(2)“1” and “2” that are permitted in spite of more restrictive language in license conditions.

5. Shall provide to the agency a copy of each individual’s:

- Certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in 641—paragraph 41.2(78)“a”; or

- NRC or agreement state license; or

- NRC master materials licensee permit; or

- Permit issued by a licensee or NRC master materials permittee of broad scope or authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

- Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

- State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)“j”(2)“2,” first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall satisfy the labeling requirements in 39.4(29)“j.”

(4) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by

direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

- (5) Nothing in this subrule relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have their reagent kits approved by the agency for use by persons licensed pursuant to 641—subrule 41.2(33) may submit the pertinent information specified in 39.4(29)“*k.*” An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in 641—subrule 41.2(33) will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25);

- (2) The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a “Notice of Claimed Investigational Exemption for a New Drug” (IND) that has been accepted by the FDA, or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

- (3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

- (4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

- (5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 641—subrule 41.2(33) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by 39.4(29)“*k.*” are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

l. Manufacture and distribution of sources or devices containing radioactive material for medical use.

- (1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration, transmission, or reference source or for the uses listed in 641—subrules 41.2(41), 41.2(43), 41.2(49), and 41.2(88) will be approved if:

1. The applicant satisfies the general requirements in 39.4(25);

2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

- The radioactive material contained, its chemical and physical form, and amount,
- Details of design and construction of the source or device,
- Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
- For devices containing radioactive material, the radiation profile of a prototype device,
- Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,
- Procedures and standards for calibrating sources and devices,
- Legend and methods for labeling sources and devices as to their radioactive content, and
- Instructions for handling and storing the source or device from the radiation safety standpoint.

These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device to persons licensed to use byproduct material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, and to persons who hold an equivalent license issued by the NRC or an agreement state; and

4. The source or device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(3) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

1. Primary containment or source capsule,
2. Protection of primary containment,
3. Method of sealing containment,
4. Containment construction materials,
5. Form of contained radioactive material,
6. Maximum temperature withstood during prototype tests,
7. Maximum pressure withstood during prototype tests,
8. Maximum quantity of contained radioactive material,
9. Radiotoxicity of contained radioactive material, and
10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 39.4(21)“d” or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 39.4(25);
2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 641—40.15(136C) of these rules; and

3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide

reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under 39.4(29)“m” only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license under 39.4(29)“m” if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 39.4(29)“m”(1) shall:

1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

2. Label or mark each unit to:

- Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

- State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

3. Ensure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: “Depleted Uranium”

4. Furnish a copy of the general license contained in 39.4(21)“d” and a copy of the agency form used to register the device to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license contained in 39.4(21)“d,” or furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission’s or agreement state’s regulation equivalent to 39.4(21)“d” and a copy of the U.S. Nuclear Regulatory Commission’s or agreement state’s certificate, or alternatively, furnish a copy of the general license contained in 39.4(21)“d” and a copy of the agency form used to register to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 39.4(21)“d”;

5. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 39.4(21)“d.” Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 39.4(21)“d” during the reporting period, the report shall so indicate;

6. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40; and shall report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29)“m” for use under a general license in that state’s regulations equivalent to 39.4(21)“d.” Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to general licensees within a particular agreement state during the reporting

period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

7. Keep records showing the name, address, and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 39.4(21)“d” or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 641—Chapters 39 and 40.

n. Rescinded IAB 7/29/09, effective 9/2/09.

o. Acceptance sampling procedures under certain specific licenses. A random sample shall be taken from each inspection lot of devices licensed under 39.4(29) for which testing is required and meet the requirements pursuant to 10 CFR 32.110.

39.4(30) Reserved.

39.4(31) *Issuance of specific licenses.*

a. Upon a determination that an application meets the requirements of the Iowa Code and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee’s receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

- (1) Minimize danger to public health and safety or property;
- (2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) Prevent loss or theft of material subject to this chapter.

c. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The applicant submits an adequate program for training radiographers and radiographers’ assistants that meets the requirements of 641—subrule 45.1(10).
- (3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.
- (4) The applicant submits written operating and emergency procedures as described in 641—subrule 45.2(4).
- (5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer’s assistant at intervals not to exceed six months as described in 641—subrule 45.1(11).

(6) The applicant submits a description of the applicant’s overall organizational structure as it applies to the radiation responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (641—paragraph 45.1(10)“d”) and potential designees responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform “in-house” calibrations of survey instruments, the applicant must describe the methods to be used and the relevant experience of the person(s) who will perform

the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 641—subrule 45.1(5).

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by 641—Chapters 38, 39, 40, and 45 will be located.

d. Specific licenses for well logging. The agency will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

(1) The applicant shall satisfy the general requirements specified in 39.4(25) and all other requirements in 641—Chapter 39, as appropriate, and any special requirements contained in 39.4(31)“*d.*”

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the agency a description of this program which specifies the following:

1. Initial training;

2. On-the-job training;

3. Annual safety reviews provided by the licensee;

4. The means the applicant will use to demonstrate the logging supervisor’s knowledge and understanding of and ability to comply with the agency’s regulations and licensing requirements and the applicant’s operating and emergency procedures; and

5. The means the applicant will use to demonstrate the logging assistant’s knowledge and understanding of and ability to comply with the applicant’s operating and emergency procedures.

(3) The applicant shall submit to the agency written operating and emergency procedures as described in 641—subrule 45.6(16) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the agency its program for annual inspections of the job performance of each logging supervisor to ensure that the agency’s regulations and license requirements and the applicant’s operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as the organizational structure applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the agency. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

39.4(32) *Specific terms and conditions of licenses.*

a. Each license issued pursuant to this chapter shall be subject to all the provisions of the Iowa Code, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing. An application for transfer of license must include:

(1) The identity and technical and financial qualifications of the proposed transferee; and

(2) The financial assurance for decommissioning information required by 39.4(26).

c. Each person licensed by the agency pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

e. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 641—subrule 41.2(34). The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 641—paragraph 41.2(34) “a” at the time of generator elution, in accordance with 641—paragraph 41.2(34) “e.”

f. Each general licensee that is required to register by 39.4(21) or 39.4(22) and each specific licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) The licensee;
- (2) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or
- (3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

The notification specified in 39.4(32) “f” shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

g. (1) Authorization under 39.4(29) “h” to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in the licensee’s consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under 39.4(29) “h” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the licensee’s consortium shall:

1. Satisfy the labeling requirements in 39.4(29) “j”(1)“4” for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of the licensee’s consortium.

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the licensee’s consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 39.4(29) “j”(3).

(3) A licensee that is a pharmacy authorized under 39.4(24) “h” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy’s consortium shall require that any individual who prepares PET radioactive drugs shall be:

1. An authorized nuclear pharmacist who meets the requirements in 39.4(29) “j”(2)“2,” or
2. An individual under the supervision of an authorized nuclear pharmacist as specified in 641—subrule 41.2(11).

(4) A pharmacy authorized under 39.4(29) “j” to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy’s consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements in 39.4(29) “j”(2)“5.”

39.4(33) *Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.*

a. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 39.4(33) not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

b. Each specific license revoked by the agency expires at the end of the day on the date of the agency’s final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of byproduct material until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

- (1) Limit actions involving byproduct material to those related to decommissioning; and
- (2) Continue to control entry to restricted areas until they are suitable for release in accordance with state of Iowa requirements.

d. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with the state of Iowa requirements, or submit within 12 months of notification a decommissioning plan, if required by 39.4(33) “*j*” and begin decommissioning upon approval of that plan if:

- (1) The license has expired pursuant to 39.4(33) “*a*” or “*b*”;
- (2) The licensee has decided to permanently cease principal activities, as defined in 641—38.2(136C) at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with state of Iowa requirements;
- (3) No principal activities under the license have been conducted for a period of 24 months; or
- (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area suitable for release in accordance with State of Iowa requirements.

e. Coincident with the notification required by 39.4(33) “*d*,” the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subrule 39.4(26) in conjunction with a license issuance or renewal or as required by this subrule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph 39.4(33) “*g*.”

- (1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective on July 9, 1997.
- (2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

f. The agency may grant a request to extend the time periods established in 39.4(33) “*d*” if the agency determines that this request is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 39.4(33) “*d*.” The schedule for decommissioning set forth in 39.4(33) “*d*” of this subrule may not commence until the agency has made a determination on the request.

g. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase the potential health and safety impacts to workers or to the public.

- (1) Procedures having potential health and safety impacts include, but are not limited to:
 1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations;
 2. Workers that would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
 3. Procedures that could result in significantly greater airborne concentrations of radioactive material than are present during operation;
 4. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 39.4(33) “*d*” of this subrule if the agency determines that the alternate schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in 39.4(33)“g” with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

1. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
2. A description of planned decommissioning activities;
3. A description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
4. A description of the planned final radiation survey; and
5. An updated detailed cost estimate for decommissioning, and a plan for ensuring the availability of adequate funds for completion of decommissioning.
6. A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.
7. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based on the criteria in paragraph “i” of this subrule.

(5) The proposed decommissioning plan will be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. Except as provided in 39.4(33)“i,” licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. When the decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

i. The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

- (1) It is technically feasible to complete decommissioning within the allotted 24-month period;
- (2) Sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;
- (3) A significant volume reduction exposure to workers can be achieved by allowing short-lived radionuclides to decay;
- (4) A significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
- (5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than a deferred cleanup, and other factors beyond the controls of the licensee.

j. As the final step in decommissioning, the licensee shall:

- (1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed IDPH Form 588-2793 or equivalent information; and
- (2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

1. Report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report the level of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per liter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

2. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the agency determines that:

- (1) Byproduct material has been properly disposed;
- (2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and
- (3) A radiation survey has been performed which demonstrates that the premises are suitable for release or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C).

(4) Records required by 39.4(52) “e” and 39.4(52) “g” have been received.

l. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

- (1) Disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 641—40.74(136C); and
- (2) Records required by 641—paragraph 40.82(2) “d.”

m. If licensed activities are transferred or assigned in accordance with 39.4(32) “b,” each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

- (1) Records of disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 641—40.74(136C); and
- (2) Records required by 641—paragraph 40.82(2) “d.”

n. Prior to license termination, each licensee shall forward the records required by 39.4(26) “g” to the agency.

39.4(34) *Renewal of licenses.*

a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24) and include the fees required in 641—subrule 38.8(2).

b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

39.4(35) *Amendment of licenses at request of licensee.* Applications for amendment of a license shall be filed in accordance with 39.4(24), include the fees required in 641—subrule 38.8(2), and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

39.4(36) *Agency action on applications to renew or amend.* In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.

39.4(37) *Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these rules.* Any person who, on the effective date of these rules, possesses a general or specific license issued by the U.S. Nuclear Regulatory Commission for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a like license issued under this chapter and the Iowa Code, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

39.4(38) *Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these rules.* Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files

an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) *Requirements for license to initially transfer source material for use under a general license.* An application for a specific license to initially transfer source material for use under 39.4(21), or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, will be approved if:

- a. The applicant satisfies the general requirements specified in 39.4(25); and
- b. The applicant submits adequate information on, and the agency approves the methods to be used for, quality control, labeling, and providing safety instructions to recipients.

39.4(40) *Conditions of licenses to initially transfer source material for use under general license: quality control, labeling, safety instructions, and records and reports.*

a. Each person licensed under 39.4(39) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words “radioactive material.”

b. Each person licensed under 39.4(39) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

c. Each person licensed under 39.4(39) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under 39.4(21) or equivalent provisions in agreement state or Nuclear Regulatory Commission regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of 39.4(21) and 39.4(41) or relevant equivalent regulations of the agreement state or Nuclear Regulatory Commission.

(2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

d. Each person licensed under 39.4(39) shall report transfers as follows:

(1) File a report with the Iowa Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;

2. For each general licensee under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(2) File a report with each responsible agreement state agency or the Nuclear Regulatory Commission that identifies all persons, operating under provisions equivalent to 39.4(21), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state or Nuclear Regulatory Commission jurisdiction:

1. The name, address, and license number of the person who transferred the source material; and

2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state or Nuclear Regulatory Commission jurisdiction.

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions during the current period, a report shall be submitted

to the agency indicating so. If no transfers have been made to general licensees in a particular agreement state or Nuclear Regulatory Commission jurisdiction during the reporting period, this information shall be reported to the responsible agreement state agency or Nuclear Regulatory Commission upon request.

e. Each person licensed under 39.4(39) shall maintain all information that supports the reports required by these rules concerning each transfer to a general licensee for a period of one year after the event is included in a report to the agency, the Nuclear Regulatory Commission or to an agreement state agency.

39.4(41) *Transfer of material.*

a. No licensee shall transfer radioactive material except as authorized pursuant to 39.4(41).

b. Except as otherwise provided in the license and subject to the provisions of 39.4(41) “*c*” and “*d*,” any licensee may transfer radioactive material:

(1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or

(5) As otherwise authorized by the agency in writing.

c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee’s license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by 39.4(41) “*c*” is acceptable:

(1) The transferor may possess and read a current copy of the transferee’s specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 39.4(41) “*d*”(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to 39.4(50) Reserved.

39.4(51) *Modification and revocation of licenses.*

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Iowa Code, or of the license, or of any rule, regulation, or order of the agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

39.4(52) Records.

a. Each person who receives source or byproduct material pursuant to a license issued pursuant to these rules shall keep records showing the receipt, transfer, and disposal of the source or byproduct material as follows:

(1) The licensee shall retain each record of receipt of the source or byproduct material as long as the material is possessed and for three years following transfer or disposition of the source or byproduct material.

(2) The licensee who transferred the material shall retain each record of transfer of the source or byproduct material until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirement.

(3) The licensee who disposed of the material shall retain each record of disposal of the source or byproduct material until the agency terminates each license that authorizes disposal of the material.

b. The licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition; the record must be retained until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirements.

c. Records which must be maintained may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. If there is a conflict between the agency's rules or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in these rules for such records shall apply unless the agency has granted a specific exemption from the record retention requirements specified in agency rules.

e. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Records of disposal of licensed material made under 641—40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)“*d.*”

f. If licensed activities are transferred or assigned, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)“*d.*”

g. Prior to license termination, each licensee shall forward the records required by subrule 39.4(26) to the agency.

39.4(53) to 39.4(89) Reserved.

39.4(90) Reciprocal recognition of licenses.

a. Licenses of byproduct, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license.

(2) The licensing document referenced in 39.4(90) "a"(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three working days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) "a."

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) "a" except by transfer to a person specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material.

(7) Notwithstanding the provisions of 39.4(90) "a"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22) "d"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22) "d" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10) "h."

b. Licenses of naturally occurring or accelerator-produced radioactive material.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90) "a"(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) "b."

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) "b" except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3) "a."

(7) Notwithstanding the provisions of 39.4(90) "b"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22) "d"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that “Removal of this label is prohibited”; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22) “d” or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer’s ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10) “h.”

39.4(91) to 39.4(104) Reserved.

[ARC 7983B, IAB 7/29/09, effective 9/2/09; ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—39.5(136C) Transportation of radioactive material.

39.5(1) All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the applicable provisions contained in 10 CFR Part 71 and 49 CFR Parts 170 through 189. The regulations in 10 CFR Part 71 apply to any licensee authorized by specific or general license to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage, or transports that material on public highways. No provision of 10 CFR Part 71 authorizes possession of licensed material.

39.5(2) The provisions of 10 CFR Part 71 are subject to the following conditions.

a. Not adopted by reference are 10 CFR 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a)-(c), 71.91(b), 71.101(c)(2), 71.101(d), 71.101(e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125.

b. Where the words “NRC”, “Commission”, “Nuclear Regulatory Commission”, “United States Nuclear Regulatory Commission” or “Administrator of the appropriate Regional Office” appear in 10 CFR Part 71, substitute the words “Iowa Department of Public Health” except when used in 10 CFR 71.5(b), 71.10, 71.17(c)(3), 71.17(e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), 71.97(c)(3)(iii), and 71.97(f).

c. The terms “certificate of compliance” and “compliance holder or applicant” apply to the NRC as it is the sole authority for issuing a package certificate of compliance.

d. Iowa form “Notice to Employees” must be posted instead of NRC Form 3 that is specified in 10 CFR Part 71.

[ARC 3746C, IAB 4/11/18, effective 5/16/18]

CHAPTER 39—APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}

Element (atomic number)	Radionuclide	Column	Column
		I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}

Element (atomic number)	Radionuclide	Column	Column
		I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of 39.4(3) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

EXAMPLE: Concentration of Radionuclide A in Product +

Exempt concentration of Radionuclide A

Concentration of Radionuclide B in Product <1

Exempt concentration of Radionuclide B

NOTE 3: To convert $\mu\text{Ci/ml}$ to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 ($2 \times 10^{-4} \mu\text{Ci/ml}$ multiplied by 37 is equivalent to $74 \times 10^{-4} \text{MBq/l}$)

CHAPTER 39—APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1

Radioactive Material	Microcuries
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10

Radioactive Material	Microcuries
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10

Radioactive Material	Microcuries
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10

Radioactive Material	Microcuries
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

NOTE 1: For purposes of 39.4(25) “f”(5)“2” where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Radionuclide A possessed}}{1000 \times \text{Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{1000 \times \text{Appendix B quantity for Radionuclide B}} \leq 1$$

NOTE 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

CHAPTER 39—APPENDIX D

LIMITS FOR BROAD LICENSES (39.4(28))

Radioactive Material	Column I curies	Column II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001

Radioactive Material	Column I curies	Column II curies
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1

Radioactive Material	Column I curies	Column II curies
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01

Radioactive Material	Column I curies	Column II curies
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01

Radioactive Material	Column I curies	Column II curies
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

CHAPTER 39—APPENDIX E
Reserved

CHAPTER 39—APPENDIX F
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY
GUARANTEES FOR PROVIDING REASONABLE ASSURANCE
OF FUNDS FOR DECOMMISSIONING

I. Introduction.

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test.

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; a ratio of current assets to current liabilities greater than 1.5; and

(2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least \$10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, or Baa as issued by Moody's; and

(2) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least \$10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform BRH within 90 days or any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the BRH of intent to establish alternate financial assurance as specified in BRH rules. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee.

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the BRH. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and BRH, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in BRH rules within 90 days after receipt by the licensee and BRH notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the BRH has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to BRH. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

CHAPTER 39—APPENDIX G

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF
THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-173	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-58	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (curies)</u>
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma ²	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha ²	.0001	20
Combinations of radioactive materials listed above ¹	—	—

¹ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Appendix G exceeds one.

² Waste packaged in Type B containers does not require an emergency plan.
[ARC 8982B, IAB 8/11/10, effective 9/15/10]

CHAPTER 39—APPENDIX H
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).
3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
2. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
3. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the agency of its intent to establish alternate financial assurance as specified in these rules within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX I
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY
COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet the following criteria:

1. Tangible net worth greater than \$10 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send notice to the agency of intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX J
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY
NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities to pass the financial test, a college or university must meet either the criteria in Section II.A.1. or the criteria in Section II.A.2. of this appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals to pass the financial test, a hospital must meet either the criteria in Section II.B.1. or the criteria in Section II.B.2. of this appendix:

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long-term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform this agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to this agency of its intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service.

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 40
STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the agency. These rules are issued pursuant to the authority in Iowa Code sections 136C.3 and 136C.4.

40.1(2) The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

40.1(3) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term “as low as is reasonably achievable” means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public interest.

40.1(4) Except as specifically provided in other parts of these rules, this chapter applies to persons licensed or registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

40.1(5) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

40.1(6) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 45.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—40.2(136C) Definitions.

40.2(1) For the purposes of this chapter, the definitions of 641—Chapter 38 may also apply.

40.2(2) As used in this chapter, these terms have the definitions set forth below.

“*Annual limit on intake (ALI)*” means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

“*Class (or lung class or inhalation class)*” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days.

“*Declared pregnant woman*” means a woman who has voluntarily informed her licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

“*Derived air concentration (DAC)*” means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour) results in an intake of one ALI. DAC values are given in Table I, Column 3, of Appendix B.

“Derived air concentration-hour (DAC-hour)” means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed dose equivalent of 5 rem (0.05 Sv).

“Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

“Inhalation class” (see “Class.”)

“Lung class” (see “Class.”)

“National tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of this chapter. In this context a “sealed source” is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

“Nonstochastic effect” means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, “deterministic effect” is an equivalent term.

“Planned special exposure” means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

“Quarter” means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

“Reference person” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, “Report of the Task Group on Reference Man.”

“Respiratory protective equipment” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive materials.

“Sanitary sewerage” means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

“Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, “probabilistic effect” is an equivalent term.

“Weighting factor” w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a0.30 results from 0.06 for each of 5 “remainder” organs, excluding the skin and the lens of the eye, that receive the highest doses.

^bFor the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

641—40.3(136C) Implementation.

40.3(1) Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

40.3(2) If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

40.3(3) If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

641—40.4 to 40.9 Reserved.

RADIATION PROTECTION PROGRAMS

641—40.10(136C) Radiation protection programs.

40.10(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See 641—40.81(136C) for record-keeping requirements relating to these programs.

40.10(2) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

40.10(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

40.10(4) To implement the ALARA requirements of 40.10(2), and notwithstanding the requirements in 641—40.26(136C), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 641—40.97(136C) and promptly take appropriate corrective action to ensure against recurrence.

641—40.11 to 40.14 Reserved.

OCCUPATIONAL DOSE LIMITS

641—40.15(136C) Occupational dose limits for adults.

40.15(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 641—40.20(136C), to the following dose limits:

a. An annual limit, which is the more limiting of:

- (1) The total effective dose equivalent being equal to 5 rem (0.05 Sv); or
- (2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

b. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

- (1) A lens dose equivalent of 15 rem (0.15 Sv), and
- (2) A shallow dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

40.15(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 40.20(5) "a" and "b."

40.15(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

40.15(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 641—40.86(136C).

40.15(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

40.15(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 40.19(5).

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.16(136C) Compliance with requirements for summation of external and internal doses.

40.16(1) If the licensee or registrant is required to monitor pursuant to both 40.37(1) and 40.37(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 40.37(1), or only pursuant to 40.37(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 40.16(2), 40.16(3) and 40.16(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

40.16(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

a. The sum of the fractions of the inhalation ALI for each radionuclide, or

b. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

c. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} , that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

40.16(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

40.16(4) Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subrule.

[ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—40.17(136C) Determination of external dose from airborne radioactive material.

40.17(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

40.17(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

641—40.18(136C) Determination of internal exposure.

40.18(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 641—40.37(136C), take suitable and timely measurements of:

- a. Concentrations of radioactive materials in air in work areas; or
- b. Quantities of radionuclides in the body; or
- c. Quantities of radionuclides excreted from the body; or
- d. Combinations of these measurements.

40.18(2) Unless respiratory protective equipment is used, as provided in 641—40.50(136C), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

40.18(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

- a. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and
- b. Upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
- c. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

40.18(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 40.8(1)“b” or 40.8(1)“c,” the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 641—40.96(136C) or 641—40.97(136C). This delay permits the licensee to make additional measurements basic to the assessments.

40.18(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

a. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

b. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

40.18(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

40.18(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

a. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 641—40.15(136C) and in complying with the monitoring requirements in 641—40.37(136C), and

b. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

c. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

40.18(8) When determining the committed effective dose equivalent, the following information may be considered:

a. In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

b. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 40.15(1) “a”(2) is met.

641—40.19(136C) Determination of prior occupational dose.

40.19(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to this rule, the licensee or registrant shall:

a. Determine the occupational radiation dose received during the current year; and

b. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

40.19(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

a. The internal and external doses from all previous planned special exposures; and

b. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

c. All lifetime cumulative occupational radiation dose.

40.19(3) In complying with the requirements of 40.19(1), a licensee or registrant may:

a. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual’s most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

b. Accept, as the record of lifetime cumulative radiation dose, a form signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual’s current employer, if the individual is not employed by the licensee or registrant; and

c. Obtain reports of the individual’s dose equivalent from the most recent employer for work involving radiation exposure, or the individual’s current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall

request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

40.19(4) a. The licensee or registrant shall record the exposure history, as required by 641—40.37(136C). The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing the exposure history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on the report indicating the periods of time for which data are not available.

b. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on or before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

40.19(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

a. In establishing administrative controls pursuant to 40.15(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

b. That the individual is not available for planned special exposures.

40.19(6) The licensee or registrant shall retain the records in 641—40.19(136C) until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing any record for this subrule for three years after the record is made.

641—40.20(136C) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 40.15(136C) provided that each of the following conditions is satisfied:

40.20(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

40.20(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

40.20(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

a. Informed of the purpose of the planned operation; and

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

40.20(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 40.19(2) during the lifetime of the individual for each individual involved.

40.20(5) Subject to 40.15(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

a. The numerical values of any of the dose limits in 40.15(1) in any year; and

b. Five times the annual dose limits in 40.15(1) during the individual's lifetime.

40.20(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 641—40.85(136C) and submits a written report in accordance with 641—40.98(136C).

40.20(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30

days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 40.15(1) but shall be included in evaluations required by 40.20(1) and 40.20(2).

641—40.21(136C) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in 641—40.15(136C).

641—40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 641—40.86(136C) for record-keeping requirements.

40.22(2) The licensee or registrant shall make efforts to avoid substantial variation¹ above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 40.22(1).

40.22(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

- a. The deep dose equivalent to the declared pregnant woman; and
- b. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

¹ The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

641—40.23 to 40.25 Reserved.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

641—40.26(136C) Dose limits for individual members of the public.

40.26(1) Each licensee or registrant shall conduct operations so that:

a. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage under 641—40.72(136C); and

b. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released under 641—subrule 41.2(27), does not exceed 0.002 rem (0.02 millisievert) in any one hour.

40.26(2) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

40.26(3) A licensee, registrant, or an applicant for a license or registration may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

a. Demonstration of the need for and the expected duration of operations in excess of the limit in 40.26(1); and

b. The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

c. The procedures to be followed to maintain the dose ALARA.

40.26(4) In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

40.26(5) The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

40.26(6) Notwithstanding the requirements of 40.26(1) "a," a licensee may permit visitors to an individual who cannot be released under 641—subrule 41.2(27) to receive a radiation dose greater than 0.1 rem (1 mSv) if:

- a. The radiation dose received does not exceed 0.5 rem (5 mSv); and
- b. The authorized user, as defined in 641—subrule 41.2(2), has determined before the visit that it is appropriate.

641—40.27(136C) Compliance with dose limits for individual members of the public.

40.27(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 40.26(136C).

40.27(2) A licensee or registrant shall show compliance with the annual dose limit in 40.26(136C) by:

a. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

b. Demonstrating that:

(1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(2) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

40.27(3) Upon approval from the agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

641—40.28(136C) Radiological criteria for license termination.

40.28(1) The criteria in this rule apply to the decommissioning of facilities licensed under 641—Chapter 39, and to the release of part of a facility or site for unrestricted use, as well as other facilities subject to the agency's jurisdiction under Iowa Code chapter 136C.

40.28(2) The criteria in this rule do not apply to sites which:

a. Have been decommissioned prior to July 1, 1999, in accordance with criteria identified in 641—subrule 39.4(33).

b. Have previously submitted and received agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the United States Nuclear Regulatory Commission (NRC) Site Decommissioning Management Plan (SDMP) Action Plan criteria; or

c. Submit a sufficient LTP or decommissioning plan prior to July 1, 1999, and such LTP or decommissioning plan is approved by the agency prior to July 1, 1999, except that if an environmental impact statement is required in the submittal, there will be a provision for day-to-day extension.

40.28(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this chapter, or after part of a facility or site has been released for unrestricted use in accordance with this chapter, the agency will require additional cleanup only if, based on new

information, it determines that the criteria of this chapter were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

40.28(4) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

40.28(5) Public notification and public participation. Upon the receipt of an LTP or decommissioning plan from the licensee or a proposal by the licensee for release of a site pursuant to 40.30(136C) or 40.31(136C) or whenever the agency deems such notice to be in the public interest, the agency shall:

a. Notify and solicit comments from:

(1) Local and state governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to 40.31(136C).

b. Publish a notice in the Iowa Administrative Bulletin and in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

40.28(6) Minimization of contamination. Applicants for licenses, other than renewals, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 641—40.10(136C) and radiological criteria for license termination in 40.28(1) through 40.28(5).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.29(136C) Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

641—40.30(136C) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

40.30(1) The licensee can demonstrate that reductions in residual radioactivity necessary to comply with the provisions of 40.29(136C) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

40.30(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

40.30(3) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

a. Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

b. Rescinded IAB 10/1/14, effective 11/5/14.

c. A statement of intent in the case of federal, state, or local government licensees, as described in 641—subparagraph 39.4(26) “*f*”(4); or

d. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

40.30(4) The licensee has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee’s intent to decommission in accordance with 641—paragraph 39.4(33) “*d*” and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and incorporated, as appropriate, following analysis of that advice. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

a. Whether provisions for institutional controls proposed by the licensee:

(1) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(2) Will be enforceable; and

(3) Will not impose undue burdens on the local community or other affected parties.

b. Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

c. In seeking advice on the issues identified in 40.30(4) “*a*,” the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

40.30(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

a. 100 mrem (1 mSv) per year; or

b. 500 mrem (5 mSv) per year provided the licensee:

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/yr (1 mSv/yr) value of 40.30(5) “*a*” are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(2) Makes provisions for durable institutional controls; and

(3) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to ensure that the institutional controls remain in place as necessary to meet the criteria of 40.30(2) and to assume and carry out responsibilities for any necessary controls and maintenance of those controls. Acceptable financial assurance mechanisms are those in subrule 40.30(3).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.31(136C) Alternate criteria for license termination.

40.31(1) The agency may terminate a license using alternate criteria greater than the dose criterion of 641—40.29(136C), 40.30(2) and 40.30(4) “*a*”(1) if the licensee:

- a.* Provides assurance that public health and safety would continue to be protected and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem/yr (1 mSv/yr) by submitting an analysis of possible sources of exposure;
- b.* Has employed, to the extent practical, restrictions on site use according to the provisions of 641—40.30(136C) in minimizing exposures at the site;
- c.* Reduces doses to ALARA levels taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;
- d.* Has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)“*d*,” and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:
 - (1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
 - (2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
 - (3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and
- e.* Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

40.31(2) The use of alternate criteria to terminate a license requires the approval of the agency after consideration of the staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to 40.32(136C).
[ARC 1639C, IAB 10/1/14, effective 11/5/14]

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

641—40.32(136C) Testing for leakage or contamination of sealed sources.

40.32(1) The licensee in possession of any sealed source shall ensure that:

- a.* Each sealed source, except as specified in 40.32(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.
- b.* Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“*l*”(2) and 39.4(29)“*l*”(3) of these rules, an agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.
- c.* Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)“*l*”(2) and 39.4(29)“*l*”(3) of these rules, an agreement state, a licensing state, or the Nuclear Regulatory Commission.
- d.* For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall ensure that the sealed source is tested for leakage or contamination before further use.
- e.* Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which

the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the “off” position.

f. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 0.001 μCi (37 Bq) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

g. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter which has a half-life greater than four days.

40.32(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

- a.* Sealed sources containing only radioactive material with a half-life of less than 30 days;
- b.* Sealed sources containing only radioactive material as a gas;
- c.* Sealed sources containing 100 μCi (3.7 MBq) or less of beta- or photon-emitting material or 10 μCi (370 kBq) or less of alpha-emitting material;
- d.* Sealed sources containing only hydrogen-3;
- e.* Seeds of iridium-192 encased in nylon ribbon; and
- f.* Sealed sources, except those used in teletherapy and brachytherapy and those containing radium, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

40.32(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, an agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission to perform such services.

40.32(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the agency.

40.32(5) The following shall be considered evidence that a sealed source is leaking:

- a.* The presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample.
- b.* Leakage of 0.001 μCi (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
- c.* The presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

40.32(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this chapter.

40.32(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 40.102(136C).

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.33 to 40.35 Reserved.

SURVEYS AND MONITORING

641—40.36(136C) Surveys and monitoring—general.

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

- a.* Are necessary for the licensee or registrant to comply with this chapter; and
- b.* Are necessary under the circumstances to evaluate:
 - (1) The magnitude and extent of radiation levels; and
 - (2) Concentrations or quantities of residual radioactivity; and
 - (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.

40.36(2) Notwithstanding 641—40.82(136C), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 641—subrule 39.4(26) as applicable.

40.36(3) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable part of these rules or a license condition.

40.36(4) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 641—40.15(136C), with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

a. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

b. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

40.36(5) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

40.36(6) After replacement, each personnel dosimeter must be sent for processing as soon as possible.

[ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

40.37(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

a. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 40.15(1);

b. Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

c. Individuals entering a high or very high radiation area;

d. Individuals working with medical fluoroscopic equipment; and

e. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv).

40.37(2) Each licensee or registrant shall monitor, to determine compliance with 641—40.18(136C), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

a. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B;

b. Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

c. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 641—40.37(136C) wear individual monitoring devices in accordance with the dosimetry vendor specifications and processed in accordance with NVLAP-approved calculation methods. Additional requirements are as follows:

a. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;

b. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 641—40.15(136C) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

c. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 641—40.15(136C), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

[ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—40.38 to 40.41 Reserved.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

641—40.42(136C) Control of access to high radiation areas.

40.42(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

a. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

b. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

c. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

40.42(2) In place of the controls required by 40.42(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

40.42(3) The licensee or registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

40.42(4) The licensee or registrant shall establish the controls required by 40.42(1) and 40.42(3) in a way that does not prevent individuals from leaving a high radiation area.

40.42(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

a. The packages do not remain in the area longer than three days; and

b. The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

40.42(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this chapter and to operate within the ALARA provisions of the licensee's radiation protection program.

40.42(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 641—40.42(136C) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.43(136C) Control of access to very high radiation areas.

40.43(1) In addition to the requirements in 641—40.42(136C), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

40.43(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 40.43(1) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.44(136C) Control of access to very high radiation areas—irradiators.

40.44(1) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

40.44(2) Each area in which there may exist radiation levels in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

a. Each entrance or access point shall be equipped with entry control devices which:

(1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(3) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in 1 hour.

b. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 40.44(2)“*a*”:

(1) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

c. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source’s shielded storage container:

(1) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

d. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

e. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 40.44(2)“*c*” and 40.44(2)“*d*.”

f. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

g. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

h. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour.

i. The entry control devices required in 40.44(2) "a" shall be tested for proper functioning. See 641—40.89(136C) for record-keeping requirements.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

j. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

k. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

40.44(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 40.44(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 40.44(2), such as those for the automatic control of radiation levels, may apply to the agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 40.44(2). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

40.44(4) The entry control devices required by 40.44(2) and 40.44(3) shall be established in such a way that no individual will be prevented from leaving the area.

641—40.45 to 40.47 Reserved.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT
INTERNAL EXPOSURE IN RESTRICTED AREAS

641—40.48(136C) Use of process or other engineering controls. The licensee shall use, to the extent practical, process or other engineering controls, such as containment, decontamination, or ventilation, to control the concentrations of radioactive material in air.

641—40.49(136C) Use of other controls.

40.49(1) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

a. Control of access;

- b.* Limitation of exposure times;
- c.* Use of respiratory protection equipment; or
- d.* Other controls.

40.49(2) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

641—40.50(136C) Use of individual respiratory protection equipment.

40.50(1) If the licensee assigns or permits the use of respiratory protection equipment to limit intakes pursuant to 641—40.49(136C):

a. The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH), except as otherwise noted in this subrule.

b. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

c. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding monitoring, including air sampling and bioassays; supervision and training of respirator user; fit testing; respirator selection; breathing air quality; inventory and control; storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; record keeping; and limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment: before the initial fitting of a face-sealing respirator; before the first field use of non-face-sealing respirators; and either every 12 months thereafter, or periodically at a frequency determined by a physician; and

(6) Fit testing, with a fit factor equal to or greater than 10 times the APF for negative pressure devices, and a fit factor equal to or greater than 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight-fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

d. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

e. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

f. Standby rescue persons are required whenever one-piece atmosphere-supplying suits or any combination of supplied air respiratory protection devices and personnel protection equipment is used from which an unaided individual would have difficulty extricating himself or herself. The standby rescue persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous

communication (visual, voice, signal line, telephone, radio, or other suitable means) with the workers, and be immediately available to assist the workers in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

g. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997, and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E)). Grade D quality air criteria include:

- (1) Oxygen content (v/v) of 19.5 to 23.5 percent;
- (2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
- (3) Carbon monoxide (CO) content of 10 ppm or less;
- (4) Carbon dioxide content of 1000 ppm or less; and
- (5) Lack of noticeable odor.

h. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face, facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

i. In the estimation of the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

40.50(2) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 641—40.49(136C), provided that the following conditions, in addition to those in 40.50(1), are satisfied:

a. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 40.49(136C) of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

b. The licensee shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Appendix A. The agency may authorize a licensee to use higher protection factors on receipt of an application that:

- (1) Describes the situation for which a need exists for higher protection factors, and
- (2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

40.50(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

40.50(4) Further restrictions.

a. The licensee shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 40.50(1) or 40.50(2).

b. The agency may impose restrictions in addition to those listed in these rules in order to:

- (1) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and
- (2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

641—40.51 to 40.53 Reserved.

STORAGE AND CONTROL OF LICENSED OR REGISTERED
SOURCES OF RADIATION

641—40.54 Reserved.

641—40.55(136C) Security and control of licensed or registered sources of radiation.

1. The licensee or registrant shall secure licensed or registered radioactive material that is stored in controlled or unrestricted areas from unauthorized removal or access.
2. The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an unrestricted area and that is not in storage.
3. The registrant shall secure registered radiation machines from unauthorized removal.
4. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.
5. Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

641—40.56 to 40.59 Reserved.

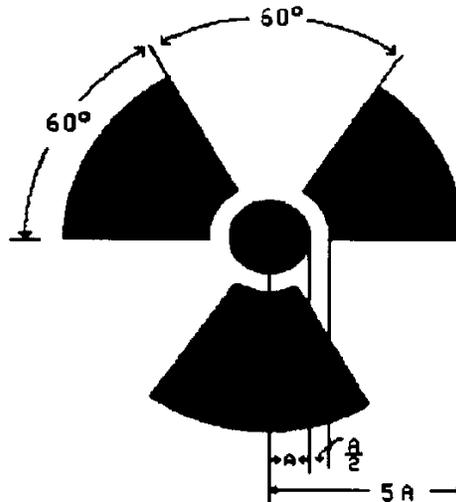
PRECAUTIONARY PROCEDURES

641—40.60(136C) Caution signs.

40.60(1) Standard radiation symbol. Unless otherwise authorized by the agency, the symbol prescribed by this rule shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



40.60(2) Exception to color requirements for standard radiation symbol. Notwithstanding the requirements of 40.60(1), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

40.60(3) Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

40.60(4) Improper posting or labeling. The licensee or registrant shall ensure that adequate measures are taken to prevent improper posting or labeling.

641—40.61(136C) Posting requirements.

40.61(1) Posting of radiation areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA”.

40.61(2) Posting of high radiation areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA”.

40.61(3) Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words “GRAVE DANGER, VERY HIGH RADIATION AREA”.

40.61(4) Posting of airborne radioactivity areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, AIRBORNE RADIOACTIVITY AREA” or “DANGER, AIRBORNE RADIOACTIVITY AREA”.

40.61(5) Posting of areas or rooms in which licensed or registered material is used or stored. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL(S)” or “DANGER, RADIOACTIVE MATERIAL(S)”.

641—40.62(136C) Exceptions to posting requirements.

40.62(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

a. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

b. The area or room is subject to the licensee's or registrant's control.

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 641—40.61(136C) provided that the patient could be released from licensee control pursuant to 641—subrule 41.2(27).

40.62(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis or simulation in the healing arts.

40.62(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 641—40.61(136C) if:

a. Access to the room is controlled pursuant to 641—subrule 41.2(53); and

b. Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

641—40.63(136C) Labeling containers and radiation machines.

40.63(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

40.63(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

40.63(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

641—40.64(136C) Exemptions to labeling requirements. A licensee is not required to label:

40.64(1) Containers holding licensed materials in quantities less than the quantities listed in Appendix C; or

40.64(2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

40.64(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter; or

40.64(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation;¹ or

40.64(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

40.64(6) Installed manufacturing or process equipment, such as piping and tanks.

¹ Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

641—40.65(136C) Procedures for receiving and opening packages.

40.65(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity shall make arrangements to receive:

- a. The package when the carrier offers it for delivery; or
- b. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

40.65(2) Each licensee shall:

a. Monitor the external surfaces of a labeled¹ package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 641—Chapter 38;

b. Monitor the external surfaces of a labeled¹ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity; and

c. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

40.65(3) The licensee shall perform the monitoring required by 40.65(2) as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

40.65(4) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the agency when:

a. Removable radioactive surface contamination exceeds the limits of 49 CFR 173.443; or

b. External radiation levels exceed the limits of 10 CFR 71.47 as set forth in rule 641—39.5(136C).

40.65(5) Each licensee shall:

a. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

b. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

40.65(6) Licensees transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 40.65(2), but are not exempt from the monitoring requirement in 40.65(2), for measuring radiation levels that ensure that the source is still properly lodged in its shield.

¹ Labeled with a Radioactive e White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

641—40.66 to 40.69 Reserved.

WASTE DISPOSAL

641—40.70(136C) General requirements.

40.70(1) A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in 641—40.74(136C) or 641—39.4(136C), or to the U.S. Department of Energy; or

b. By decay in storage; or

c. By release in effluents within the limits in 40.72(1) "d"; or

d. As authorized pursuant to 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), 641—40.74(136C), or 641—40.77(136C).

40.70(2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

a. Treatment prior to disposal; or

b. Treatment or disposal by incineration; or

c. Decay in storage; or

d. Storage until transferred to a storage or disposal facility authorized to receive the waste.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.71(136C) Method for obtaining approval of proposed disposal procedures. A licensee or applicant for a license may apply to the agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

40.71(1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

40.71(2) An analysis and evaluation of pertinent information on the nature of the environment; and

40.71(3) The nature and location of other potentially affected facilities; and

40.71(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this chapter.

641—40.72(136C) Disposal by release into sanitary sewerage.

40.72(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

a. The material is readily soluble, or is readily dispersible biological material, in water; and

b. The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

c. If more than one radionuclide is released, the following conditions must also be satisfied:

(1) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(2) The sum of the fractions for each radionuclide required by 40.72(1) "c"(1) does not exceed unity; and

d. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 Ci (185 GBq) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

40.72(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 40.72(1).

641—40.73(136C) Treatment or disposal by incineration. A licensee may treat or dispose of licensed materials by incineration only in the amounts and forms specified in 641—40.74(136C) or as specifically approved by the agency pursuant to 641—40.71(136C).

641—40.74(136C) Disposal of specific wastes.

40.74(1) A licensee may dispose of the following licensed material as if it were not radioactive:

a. 0.05 μ Ci (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

b. 0.05 μ Ci (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

40.74(2) A licensee shall not dispose of tissue pursuant to 40.74(1) "b" in a manner that would permit its use either as food for humans or as animal feed.

40.74(3) The licensee shall maintain records in accordance with 641—40.88(136C).

641—40.75(136C) Transfer for disposal and manifests.

40.75(1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

40.75(2) Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix D of this chapter.

40.75(3) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D of this chapter.

40.75(4) Any licensee shipping licensed material, as defined in paragraphs “3” and “4” of the definition of “byproduct material” set forth in 641—Chapter 38, intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.76(136C) Compliance with environmental and health protection regulations. Nothing in 641—40.70(136C), 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), 641—40.74(136C), or 641—40.75(136C) relieves the licensee or registrant from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 641—40.70(136C), 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), 641—40.74(136C), or 641—40.75(136C).

641—40.77(136C) Disposal of certain byproduct material.

40.77(1) Licensed material, as defined in paragraphs “3” and “4” of the definition of “byproduct material” set forth in 641—Chapter 38, may be disposed of in accordance with 10 CFR Part 61, even though the material is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of 641—40.75(136C).

40.77(2) A licensee may dispose of licensed material, as defined in paragraphs “3” and “4” of the definition of “byproduct material” set forth in 641—Chapter 38, at a disposal facility authorized to dispose of such material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

641—40.78 and 40.79 Reserved.

RECORDS

641—40.80(136C) General provisions.

40.80(1) Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

40.80(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

40.80(3) In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in 40.80(1). However, all quantities must be recorded as stated in 40.80(1).

40.80(4) Notwithstanding the requirements of 40.80(1), when recording information on shipment manifests, as required in 641—40.75(136C), information must be recorded in the International System of Units (SI) or in SI and units as specified in 40.80(1).

40.80(5) Notwithstanding the requirements of 40.80(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

641—40.81(136C) Records of radiation protection programs.

40.81(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

- a.* The provisions of the program; and
- b.* Audits and other reviews of program content and implementation.

40.81(2) The licensee or registrant shall retain the records required by 40.81(1)“*a*” until the agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 40.81(1)“*b*” for three years after the record is made.

641—40.82(136C) Records of surveys.

40.82(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 641—40.36(136C) and 40.65(2). The licensee or registrant shall retain these records for three years after the record is made.

40.82(2) The licensee or registrant shall retain each of the following records until the agency terminates each pertinent license or registration requiring the record:

- a.* Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and
- b.* Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
- c.* Records showing the results of air sampling, surveys, and bioassays required pursuant to 40.50(1)“*c*”(1) and 40.50(1)“*c*”(2); and
- d.* Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

40.82(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 641—40.82(136C) or shall make provisions with the agency for transfer to the agency.

641—40.83(136C) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by 641—40.32(136C) shall be kept in units of microcurie or becquerel and maintained for inspection by the agency for five years after the records are made.

641—40.84(136C) Records of prior occupational dose.

40.84(1) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 641—40.19(136C) until the agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing the record required in 641—40.84(136C) for three years after the record is made.

40.84(2) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 641—40.84(136C) or shall make provisions with the agency for transfer to the agency.

641—40.85(136C) Records of planned special exposures.

40.85(1) For each use of the provisions of 641—40.20(136C) for planned special exposures, the licensee or registrant shall maintain records that describe:

- a.* The exceptional circumstances requiring the use of a planned special exposure; and
- b.* The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- c.* What actions were necessary; and
- d.* Why the actions were necessary; and
- e.* What precautions were taken to assure that doses were maintained ALARA; and
- f.* What individual and collective doses were expected to result; and

g. The doses actually received in the planned special exposure.

40.85(2) The licensee or registrant shall retain the records until the agency terminates each pertinent license or registration requiring these records.

40.85(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 641—40.85(136C) or shall make provisions with the agency for transfer to the agency.

641—40.86(136C) Records of individual monitoring results.

40.86(1) Record-keeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 641—40.37(136C), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect on or before January 1, 1994, need not be changed. These records shall include, when applicable:

- a. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- b. The estimated intake of radionuclides, see 641—40.16(136C); and
- c. The committed effective dose equivalent assigned to the intake of radionuclides; and
- d. The specific information used to calculate the committed effective dose equivalent pursuant to 40.18(3); and
- e. The total effective dose equivalent when required by 641—40.16(136C); and
- f. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

40.86(2) Record-keeping frequency. The licensee or registrant shall make entries of the records specified in 40.86(1) at intervals not to exceed one year.

40.86(3) Record-keeping format. The licensee or registrant shall maintain the records specified in 40.86(1) in clear and legible form.

40.86(4) Embryo/Fetus records. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

40.86(5) Retention during license or registration. The licensee or registrant shall retain each required form or record until the agency terminates each pertinent license or registration requiring the record.

40.86(6) Retention after termination. Upon termination of the license or registration, the licensee or registrant shall permanently store records required in 641—40.86(136C) or shall make provision with the agency for transfer to the agency.

641—40.87(136C) Records of dose to individual members of the public.

40.87(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 641—40.26(136C).

40.87(2) The licensee or registrant shall retain the records required by this rule until the agency terminates each pertinent license or registration requiring the record.

641—40.88(136C) Records of waste disposal.

40.88(1) Each licensee shall maintain records of the disposal of licensed materials made pursuant to 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), 641—40.74(136C), and disposal or burial in soil.

40.88(2) The licensee shall retain the records required by 40.88(1) until the agency terminates each pertinent license or registration requiring the record.

641—40.89(136C) Records of testing entry control devices for very high radiation areas.

40.89(1) Each licensee or registrant shall maintain records of tests made pursuant to 40.44(2) “j” on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

40.89(2) The licensee or registrant shall retain the records required by 40.89(1) for three years after the record is made.

641—40.90(136C) Form of records.

40.90(1) Each record required by Chapter 40 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

40.90(2) The licensee or registrant shall retain the records required by Chapter 40 until the agency terminates each pertinent license or registration requiring the record.

641—40.91 to 40.94 Reserved.

REPORTS

641—40.95(136C) Reports of stolen, lost, or missing licensed or registered sources of radiation.

40.95(1) Telephone reports. Each licensee or registrant shall report to the agency by telephone as follows:

a. Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

b. Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in quantity greater than ten times the quantity specified in Appendix C that is still missing.

c. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

40.95(2) Written reports. Each licensee or registrant required to make a report pursuant to 40.95(1) shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

a. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

b. A description of the circumstances under which the loss or theft occurred; and

c. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

d. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

e. Actions that have been taken, or will be taken, to recover the source of radiation; and

f. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

40.95(3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

40.95(4) The licensee or registrant shall prepare any report filed with the agency pursuant to 641—40.95(136C) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

641—40.96(136C) Notification of incidents.

40.96(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

a. An individual to receive:

- (1) A total effective dose equivalent of 25 rem (0.25 Sv) or more; or
- (2) A lens dose equivalent of 75 rem (0.75 Sv) or more; or
- (3) A shallow dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more; or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. In addition to the requirements of paragraphs “*a*” and “*b*” above, each licensee shall notify the Iowa department of public health as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, and other such events).

40.96(2) Twenty-four-hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

a. An individual to receive, in a period of 24 hours:

- (1) A total effective dose equivalent exceeding 5 rem (0.05 Sv); or
- (2) A lens dose equivalent exceeding 15 rem (0.15 Sv); or
- (3) A shallow dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv); or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

c. In addition to the requirements of paragraphs “*a*” and “*b*” above, each licensee shall notify the Iowa department of public health within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
2. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B for the material; and
3. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
2. The equipment is required to be available and operable when it is disabled or fails to function; and
3. No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual’s clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

1. The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B for the material; and

2. The damage affects the integrity of the licensed material or its container.

40.96(3) The licensee or registrant shall prepare each report filed with the agency pursuant to 641—40.96(136C) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

40.96(4) Licensees or registrants shall make the reports required by 40.96(1) and 40.96(2) to the agency by telephone, telegram, mailgram, or facsimile.

a. Licensees or registrants making initial reports to the Iowa department of public health shall to the extent that the information is available at the time of notification include:

- (1) The caller's name and call-back telephone number;
- (2) A description of the event, including date and time;
- (3) The exact location of the event;
- (4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (5) Any personnel radiation exposure data available.

b. Each licensee or registrant who makes a report required by 40.96(1) or 40.96(2) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information. These written reports must be sent to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319. The reports must include the following:

- (1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (2) The exact location of the event;
- (3) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (4) Date and time of the event;
- (5) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

40.96(5) The provisions of 641—40.96(136C) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 641—40.98(136C).

641—40.97(136C) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

40.97(1) Reportable events. In addition to the notification required by 40.96(136C), each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

a. Incidents for which notification is required by 641—40.96(136C); or

b. Doses in excess of any of the following:

- (1) The occupational dose limits for adults in 641—40.15(136C); or
- (2) The occupational dose limits for a minor in 641—40.21(136C); or
- (3) The limits for an individual member of the public in 641—40.26(136C); or
- (4) Any applicable limit in the license or registration; or
- (5) The ALARA constraints for air emissions established under 641—40.10(136C); or
- (6) The limits for an embryo/fetus of a declared pregnant woman in 641—40.22(136C).

c. Levels of radiation or concentrations of radioactive material in:

- (1) A restricted area in excess of applicable limits in the license or registration; or
- (2) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 641—40.26(136C); or

d. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

40.97(2) Contents of reports.

a. Each report required by 40.97(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

- (1) Estimates of each individual's dose; and
- (2) The levels of radiation and concentrations of radioactive material involved; and
- (3) The cause of the elevated exposures, dose rates, or concentrations; and
- (4) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

Each report filed pursuant to this paragraph must include the name, social security number, and date of birth for each occupationally overexposed individual. The report must be prepared so that this information is stated in a separate and detachable part of the report.

b. Each report filed pursuant to 40.97(1) shall include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus in 40.22(136C), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

40.97(3) All licensees or registrants who make reports pursuant to 641—40.97(136C) or 641—40.98(136C) to the agency regarding exposure of an identified occupationally exposed individual, or of an identified member of the public, to radiation or radioactive material shall also provide a copy of the report to the individual or member of the public. Transmittal shall be at the same time as the transmittal to the agency.

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641—40.98(136C) Reports of planned special exposures. The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with 641—40.20(136C) informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 641—40.85(136C).

641—40.99(136C) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subrules 40.99(1) to 40.99(5) for each type of transaction.

40.99(1) Each licensee that manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The manufacturer, model, and serial number of the source;
- d.* The radioactive material in the source;
- e.* The initial source strength in becquerels (curies) at the time of manufacture; and
- f.* The manufacture date of the source.

40.99(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The name and license number of the recipient facility and the shipping address;
- d.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e.* The radioactive material in the source;

- f.* The initial or current source strength in becquerels (curies);
- g.* The date for which the source strength is reported;
- h.* The shipping date;
- i.* The estimated arrival date; and
- j.* For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The name, address, and license number of the person that provided the source;
- d.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e.* The radioactive material in the source;
- f.* The initial or current source strength in becquerels (curies);
- g.* The date for which the source strength is reported;
- h.* The date of receipt; and
- i.* For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- d.* The radioactive material in the source;
- e.* The initial or current source strength in becquerels (curies);
- f.* The date for which the source strength is reported; and
- g.* The disassemble date of the source.

40.99(5) Each licensee that disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a.* The name, address, and license number of the reporting licensee;
- b.* The name of the individual preparing the report;
- c.* The waste manifest number;
- d.* The container identification with the nationally tracked source;
- e.* The date of disposal; and
- f.* The method of disposal.

40.99(6) Reports discussed in subrules 40.99(1) to 40.99(5) must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

- a.* The on-line National Source Tracking System;
- b.* Electronically using a computer-readable format;
- c.* By facsimile;
- d.* By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
- e.* By telephone with follow-up by facsimile or mail.

40.99(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System.

The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subrules 40.99(1) to 40.99(5). By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

40.99(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified in subrule 40.99(6). The initial inventory report must include the following information:

- a. The name, address, and license number of the reporting licensee;
- b. The name of the individual preparing the report;
- c. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
- d. The radioactive material in the sealed source;
- e. The initial or current source strength in becquerels (curies); and
- f. The date for which the source strength is reported.

641—40.100(136C) Reports of individual monitoring.

40.100(1) This section applies to each person licensed or registered by the agency to:

- a. Possess or use sources of radiation for purposes of industrial radiography pursuant to 641—39.4(136C) and 641—Chapter 45; or
- b. Receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61 of federal regulations or appropriate other agreement state regulations; or
- c. Possess or use at any time, for processing or manufacturing for distribution pursuant to 641—39.4(136C) or 641—41.2(136C), radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity ^a	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

^a The agency may require as a license condition, or by rule, regulation, or order pursuant to 40.105(136C), reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

40.100(2) Each licensee or registrant in a category listed in 40.100(1) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 641—40.36(136C) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required.

40.100(3) The licensee or registrant shall file the report required by 40.100(2), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the agency.

641—40.101(136C) Notifications and reports to individuals.

40.101(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 641—40.112(136C).

40.101(2) When a licensee or registrant is required pursuant to 641—40.97(136C), 641—40.98(136C), or 641—40.100(136C) to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to this agency to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of 40.112(1).

641—40.102(136C) Reports of leaking or contaminated sealed sources. The licensee shall file a report within five days with the agency if the test for leakage or contamination required pursuant to 641—40.32(136C) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

641—40.103 and 40.104 Reserved.

ADDITIONAL REQUIREMENTS

641—40.105(136C) Vacating premises. Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of their activities, notify the agency in writing of intent to vacate. When deemed necessary by the agency, the licensee shall decontaminate the premises in such a manner as the agency may specify.

641—40.106 to 40.109 Reserved.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

641—40.110(136C) Posting of notices to workers.

40.110(1) Each licensee or registrant, except those registrants with diagnostic X-ray systems, shall post current copies of the following documents:

- a.* This subrule and 641—Chapter 40;
- b.* The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
- c.* The operating procedures applicable to activities under the license or registration; and
- d.* Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 641—Chapter 38, and any response from the licensee or registrant.

40.110(2) If posting of a document specified in 40.110(1) “*a*,” 40.110(1) “*b*” and 40.110(1) “*c*” is not practical, the licensee or registrant may post a notice which describes the document and states where it may be examined.

40.110(3) Agency Form “Notice to Employees” shall be posted by each licensee or registrant.

40.110(4) Agency documents posted pursuant to 40.110(1) “*d*” shall be posted within two working days after receipt of the documents from the agency; the licensee’s or registrant’s response, if any, shall be posted within two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

40.110(5) Documents, notices, or forms posted pursuant to 40.110(1) shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

641—40.111(136C) Instructions to workers.

40.111(1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv):

- a.* Shall be kept informed of the storage, transfer, or use of sources of radiation;
- b.* Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;
- c.* Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;
- d.* Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these rules, and licenses or unnecessary exposure to radiation or radioactive material;
- e.* Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
- f.* Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 641—40.112(136C).
- g.* The instruction in “*b*” through “*f*” above shall be conducted at least annually.
- h.* Shall be commensurate with potential radiological health protection problems present in the workplace.

40.111(2) In determining those individuals subject to the requirements of 40.111(1), consideration must be given to assigning activities during normal and abnormal situations involving exposure to sources of radiation which can reasonably be expected to occur during the life of the facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

641—40.112(136C) Notifications and reports to individuals.

40.112(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in subrule 40.112(2). The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 641—40.86(136C). Each notification and report shall:

- a.* Be in writing;
- b.* Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;
- c.* Include the individual's exposure information; and
- d.* Contain the following statement:

“This report is furnished to you under the provisions of 641—40.112(136C) of Iowa's Radiation Machine and Radioactive Materials rules. You should preserve this report for further reference.”

40.112(2) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of 641—40.86(136C). The licensee or registrant shall provide to each individual monitored under 641—40.37(136C) an annual report of the dose received in that monitoring year if:

- a.* The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue, or
- b.* The individual requests the individual's annual dose report.

40.112(3) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 641—40.37(136C). Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources

of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

40.112(4) When a licensee or registrant is required pursuant to 641—40.96(136C), 641—40.97(136C), or 641—40.98(136C) to report to the agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the individual's exposure data included in the report to the agency. Such reports shall be transmitted at a time not later than the transmittal to the agency.

40.112(5) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

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641—40.113(136C) Presence of representatives of licensees or registrants and workers during inspection.

40.113(1) Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

40.113(2) During an inspection, agency inspectors may consult privately with workers as specified in 40.114(136C). The licensee or registrant may accompany agency inspectors during other phases of an inspection.

40.113(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

40.113(4) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 641—40.111(136C).

40.113(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.

40.113(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

40.113(7) Notwithstanding the other provisions of 641—40.113(136C), agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

641—40.114(136C) Consultation with workers during inspections.

40.114(1) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

40.114(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules, or license condition,

or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 40.115(1).

40.114(3) The provisions of 40.114(2) shall not be interpreted as authorization to disregard instructions pursuant to 641—40.111(136C).

641—40.115(136C) Requests by workers for inspections.

40.115(1) Any worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Bureau of Radiological Health, no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

40.115(2) If, upon receipt of such notice, the Bureau of Radiological Health determines that the complaint meets the requirements set forth in 40.116(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 641—40.116(136C) need not be limited to matters referred to in the complaint.

40.115(3) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this chapter.

641—40.116(136C) Inspections not warranted—informal review.

40.116(1) a. If the Bureau of Radiological Health determines, with respect to a complaint under this rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau of Radiological Health shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Attorney General's Office. Such agency will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Attorney General's Office. Such agency will provide the complainant with a copy of such statement by certified mail.

b. Upon the request of the complainant, the Attorney General's Office may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Attorney General's Office shall affirm, modify, or reverse the determination of the Radiation Control Program and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

40.116(2) If the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of 40.116(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 40.116(1).

641—40.117(136C) Employee protection.

40.117(1) Discrimination by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant against an employee for engaging in certain

protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in 641—Chapters 38 to 45 and in general are related to the administration or enforcement of requirements imposed under 641—Chapters 38 to 45.

a. The protected activities include but are not limited to:

(1) Providing the agency or the individual's employer information about alleged violations of either of the statutes named in this rule or possible violations of requirements imposed under either of those statutes;

(2) Refusing to engage in any practice made unlawful under either of the statutes named in this rule or under these requirements if the employee has identified the alleged illegality to the employer;

(3) Requesting that the agency institute action against the individual's employer for the administration or enforcement of these requirements;

(4) Testifying in any agency proceeding, or before Congress, or at any federal or state proceeding regarding any provision (or proposed provision) of federal statutes or these rules;

(5) Assisting or participating in, or about to assist or participate in, these activities.

b. These activities are protected even if no formal proceeding is actually initiated as a result of the employee's assistance or participation.

c. This rule has no application to any employee alleging discrimination prohibited by this rule who, acting without direction from the individual's employer (or the employer's agent), deliberately causes a violation of any requirement of 641—Chapters 38 to 45.

40.117(2) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in 40.117(1)“a” may seek a remedy for the discharge or discrimination through an administrative proceeding in the U.S. Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may file for the administrative proceeding by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

40.117(3) A violation of 40.117(1)“a”(1) or 40.117(1)“a”(4) by a licensee or registrant, an applicant for a license or registration, or a contractor or subcontractor of a licensee or applicant may be grounds for:

a. Denial, revocation, or suspension of the license or registration.

b. Imposition of a civil penalty on the licensee, registrant, or applicant.

c. Other enforcement action.

40.117(4) Actions taken by an employer or others which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render the employee immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

40.117(5) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to 641—Chapters 38 to 45, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in 40.117(1)“a” including, but not limited to, providing information to the agency or to the individual's employer on potential violations or other matters within the agency's regulatory responsibilities.

CHAPTER 40

APPENDIX A

PROTECTION FACTORS FOR RESPIRATORS^a

	Operating Mode	Assigned Protection Factor
I. Air-Purifying Respirators (particulate 1A ^b only) 1A ^c :		
Filtering facepiece disposable ^d	Negative Pressure	(^d)
Facepiece, half ^e	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere-Supplying Respirators (particulate, gases and vapors 1A ^f):		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	(^g)
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	^h 100
Facepiece, full	Pressure Demand	ⁱ 10,000
Facepiece, full	Demand, Recirculating	^h 100
Facepiece, full	Positive Pressure Recirculating	ⁱ 10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above	

^aThese assigned protection factors apply only in a respiratory protection program that meets the requirement of 641—Chapter 40. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table I, Column 3, of Appendix B to 641—Chapter 40 are based on internal dose due to inhalation may, in addition, present external exposure

hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

^bAir-purifying respirators with $APF < 100$ must be equipped with particulate filters that are at least 95 percent efficient. Air-purifying respirators with $APF = 100$ must be equipped with particulate filters that are at least 99 percent efficient. Air-purifying respirators with $APF > 100$ must be equipped with particulate filters that are at least 99.97 percent efficient.

^cThe licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

^dLicensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for the use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 641—40.50(136C) apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

^eUnder-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient, and all other requirements of 641—Chapter 40 are met.

^fThe assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

^gNo NIOSH approval schedule is currently available for atmosphere-supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met.

^hThe licensee should implement institutional controls to ensure that these devices are not used in areas immediately dangerous to life or health.

ⁱThis type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

CHAPTER 40

APPENDIX B

ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS
(DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT
CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm , micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

NOTE: The values in Tables I, II, and III are presented in the computer “E” notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^2 or 600, and 6E+0 represents 6×10^0 or 6.

TABLE I “OCCUPATIONAL VALUES”

Note that the columns in Table I of this appendix captioned “Oral Ingestion ALI,” “Inhalation ALI,” and “DAC,” are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by “Reference Person” which would result in either (1) a committed effective dose equivalent of 5 rem (0.05 Sv), stochastic ALI, or (2) a committed dose equivalent of 50 rem (0.5 Sv) to an organ or tissue, nonstochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rem (0.05 Sv). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in 40.2. The nonstochastic ALIs were derived to avoid nonstochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the “remainder” category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract—stomach, small intestine, upper large intestine, and lower large intestine—are to be treated as four separate organs.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rem (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall	=	lower large intestine wall;
St. wall	=	stomach wall;
Blad wall	=	bladder wall; and
Bone surf	=	bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and nonstochastic ALIs, will ensure that nonstochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the nonstochastic ALI is limiting, use of that nonstochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50 rem (0.5 Sv) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, Σ (intake (in μCi) of each radionuclide/ ALI_{ns}) ≤ 1.0 . If there is an external deep dose equivalent contribution of H_d , then this sum must be less than $1 - (H_d/50)$, instead of ≤ 1.0 .

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$DAC = ALI(\text{in } \mu\text{Ci}) / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = [ALI / 2.4 \times 10^9] \mu\text{Ci/ml}$, where 2×10^4 ml is the volume of air breathed per minute at work by Reference Person under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 641—40.16(136C). When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

TABLE II “EFFLUENT CONCENTRATIONS”

The columns in Table II of this appendix captioned “Effluents,” “Air” and “Water” are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 641—40.27(136C). The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (0.5 mSv).

Consideration of nonstochastic limits has not been included in deriving the air and water effluent concentration limits because nonstochastic effects are presumed not to occur at or below the dose levels

established for individual members of the public. For radionuclides, where the nonstochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as they were in Appendix A of this chapter of the eighth edition of Volume I of the Suggested State Regulations for Control of Radiation.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5 rem (0.05 Sv) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7 . The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of Reference Person.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

TABLE III "RELEASES TO SEWERS"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 40.72. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by Reference Person, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Person during a year, would result in a committed effective dose equivalent of 0.5 rem.

LIST OF ELEMENTS

Atomic			Atomic		
Name	Symbol	Number	Name	Symbol	Number
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybdenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Antimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Nitrogen	N	7
Barium	Ba	56	Osmium	Os	76
Berkelium	Bk	97	Oxygen	O	8
Beryllium	Be	4	Palladium	Pd	46
Bismuth	Bi	83	Phosphorus	P	15

Bromine	Br	35	Platinum	Pt	78
Cadmium	Cd	48	Plutonium	Pu	94
Calcium	Ca	20	Polonium	Po	84
Californium	Cf	98	Potassium	K	19
Carbon	C	6	Praseodymium	Pr	59
Cerium	Ce	58	Promethium	Pm	61
Cesium	Cs	55	Protactinium	Pa	91
Chlorine	Cl	17	Radium	Ra	88
Chromium	Cr	24	Radon	Rn	86
Cobalt	Co	27	Rhenium	Re	75
Copper	Cu	29	Rhodium	Rh	45
Curium	Cm	96	Rubidium	Rb	37
Dysprosium	Dy	66	Ruthenium	Ru	44
Einsteinium	Es	99	Samarium	Sm	62
Erbium	Er	68	Scandium	Sc	21
Europium	Eu	63	Selenium	Se	34
Fermium	Fm	100	Silicon	Si	14
Fluorine	F	9	Silver	Ag	47
Francium	Fr	87	Sodium	Na	11
Gadolinium	Gd	64	Strontium	Sr	38
Gallium	Ga	31	Sulfur	S	16
Germanium	Ge	32	Tantalum	Ta	73
Gold	Au	79	Technetium	Tc	43
Hafnium	Hf	72	Tellurium	Te	52
Holmium	Ho	67	Terbium	Tb	65
Hydrogen	H	1	Thallium	Tl	81
Indium	In	49	Thorium	Th	90
Iodine	I	53	Thulium	Tm	69
Iridium	Ir	77	Tin	Sn	50
Iron	Fe	26	Titanium	Ti	22
Krypton	Kr	36	Tungsten	W	74
Lanthanum	La	57	Uranium	U	92
Lead	Pb	82	Vanadium	V	23
Lutetium	Lu	71	Xenon	Xe	54
Magnesium	Mg	12	Ytterbium	Yb	70
Manganese	Mn	25	Yttrium	Y	39
Mendelevium	Md	101	Zinc	Zn	30
			Zirconium	Zr	40

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	ALI (μCi)				DAC (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T ₂) Submersion ¹ : Use above values as HT and T ₂ oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ⁷ Be	1E+3	2E+2	6E-8	2E-10	-	-
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4
		Y, see ⁷ Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11 ²	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
8	Oxygen-15 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
9	Fluorine-18 ²	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)
		Oral Ingestion ALI (μCi)	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
			ALI (μCi)	DAC ($\mu\text{Ci/ml}$)			
14 Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
	Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14 Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
	LLI wall	(3E+3)	-	-	-	4E-5	4E-4
	W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
15 Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
	W, phosphates of Zn^{2+} , S^{3+} , Mg^{2+} , Fe^{3+} , Bi^{3+} , and lanthanides	-	4E+2	2E-7	5E-10	-	-
	Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15 Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
	W, see ^{32}P	-	3E+3	1E-6	4E-9	-	-
16 Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
	D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
	LLI wall	(8E+3)	-	-	-	1E-4	1E-3
17 Chlorine-36	W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3	-	-	-	-	-
	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
17	Chlorine-38 ²	D, see ³⁶ Cl	2E+4	4E+4	2E-5	6E-8	-	-
		St wall	(3E+4)	-	-	-	3E-4	3E-3
		W, see ³⁶ Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39 ²	D, see ³⁶ Cl	2E+4	5E+4	2E-5	7E-8	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ³⁶ Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	Submersion ¹	-	-	1E+0	6E-3	-	-
18	Argon-39	Submersion ¹	-	-	2E-4	8E-7	-	-
18	Argon-41	Submersion ¹	-	-	3E-6	1E-8	-	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44 ²	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45 ²	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
		Bone surf	(4E+3)	(4E+3)	-	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall	(3E+3)	-	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49 ²	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
		Y, SrTiO	-	6E+0	2E-9	8E-12	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
22 Titanium-45	D, see ⁴⁴ Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	W, see ⁴⁴ Ti	-	4E+4	1E-5	5E-8	-	-
	Y, see ⁴⁴ Ti	-	3E+4	1E-5	4E-8	-	-
23 Vanadium-47 ²	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
	St wall	(3E+4)	-	-	-	4E-4	4E-3
23 Vanadium-48	W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
	D, see ⁴⁷ V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
23 Vanadium-49	W, see ⁴⁷ V	-	6E+2	3E-7	9E-10	-	-
	D, see ⁴⁷ V	7E+4	3E+4	1E-5	-	-	-
24 Chromium-48	LLI wall	(9E+4)	(3E+4)	-	5E-8	1E-3	1E-2
	Bone surf	-	2E+4	8E-6	2E-8	-	-
	W, see ⁴⁷ V	-	2E+4	8E-6	2E-8	-	-
24 Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
	Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24 Chromium-49 ²	D, see ⁴⁸ Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
	W, see ⁴⁸ Cr	-	1E+5	4E-5	1E-7	-	-
	Y, see ⁴⁸ Cr	-	9E+4	4E-5	1E-7	-	-
24 Chromium-51	D, see ⁴⁸ Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
	W, see ⁴⁸ Cr	-	2E+4	1E-5	3E-8	-	-
	Y, see ⁴⁸ Cr	-	2E+4	8E-6	3E-8	-	-
25 Manganese-51 ²	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
	W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
25 Manganese-52m ²	D, see ⁵¹ Mn	3E+4	9E+4	4E-5	1E-7	-	-
	St wall	(4E+4)	-	-	-	5E-4	5E-3
	W, see ⁵¹ Mn	-	1E+5	4E-5	1E-7	-	-
25 Manganese-52	D, see ⁵¹ Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
	W, see ⁵¹ Mn	-	9E+2	4E-7	1E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
			ALI (μCi)	ALI (μCi)				DAC ($\mu\text{Ci/ml}$)
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
				Bone surf				
			-	(2E+4)	-	3E-8	-	-
		W, see ^{51}Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	-	-
27	Cobalt-60m ²	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	-	-
		St wall	(1E+6)	-	-	-	2E-2	2E-1
		Y, see ^{55}Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-61 ²	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
27	Cobalt-62m ²	W, see ⁵⁵ Co	4E+4	2E+5	7E-5	2E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
		Y, see ⁵⁵ Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see ⁵⁶ Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ⁵⁶ Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see ⁵⁶ Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ⁵⁶ Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see ⁵⁶ Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ⁵⁶ Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see ⁵⁶ Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ⁵⁶ Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see ⁵⁶ Ni	4E+2	2E+3	7E-7	2E-9	-	-
		LLI wall	(5E+2)	-	-	-	6E-6	6E-5
		W, see ⁵⁶ Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60 ²	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
		St wall	(3E+4)	-	-	-	4E-4	4E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see ⁶⁰ Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ⁶⁰ Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see ⁶⁰ Cu	-	4E+4	1E-5	5E-8	-	-
29	Copper-64	D, see ⁶⁰ Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ⁶⁰ Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see ⁶⁰ Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see ⁶⁰ Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ⁶⁰ Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see ⁶⁰ Cu	-	5E+3	2E-6	6E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
			ALI (μCi)	ALI (μCi)				DAC ($\mu\text{Ci/ml}$)
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63 ²	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69 ²	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65 ²	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ⁶⁵ Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ⁶⁵ Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ⁶⁵ Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ⁶⁵ Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68 ²	D, see ⁶⁵ Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ⁶⁵ Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70 ²	D, see ⁶⁵ Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see ⁶⁵ Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see ⁶⁵ Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ⁶⁵ Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see ⁶⁵ Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ⁶⁵ Ga	-	2E+4	6E-6	2E-8	-	-
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67 ²	D, see ⁶⁶ Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see ⁶⁶ Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see ⁶⁶ Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ⁶⁶ Ge	-	1E+2	4E-8	1E-10	-	-
32	Germanium-69	D, see ⁶⁶ Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ⁶⁶ Ge	-	8E+3	3E-6	1E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
32 Germanium-71	D, see ⁶⁶ Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
	W, see ⁶⁶ Ge	-	4E+4	2E-5	6E-8	-	-
32 Germanium-75 ²	D, see ⁶⁶ Ge	4E+4	8E+4	3E-5	1E-7	-	-
	St wall	(7E+4)	-	-	-	9E-4	9E-3
	W, see ⁶⁶ Ge	-	8E+4	4E-5	1E-7	-	-
32 Germanium-77	D, see ⁶⁶ Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
	W, see ⁶⁶ Ge	-	6E+3	2E-6	8E-9	-	-
32 Germanium-78 ²	D, see ⁶⁶ Ge	2E+4	2E+4	9E-6	3E-8	-	-
	St wall	(2E+4)	-	-	-	3E-4	3E-3
	W, see ⁶⁶ Ge	-	2E+4	9E-6	3E-8	-	-
33 Arsenic-69 ²	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
	St wall	(4E+4)	-	-	-	6E-4	6E-3
33 Arsenic-70 ²	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33 Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33 Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33 Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33 Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
	LLI wall	(5E+3)	-	-	-	6E-5	6E-4
33 Arsenic-78 ²	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34 Selenium-70 ²	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
	W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-
34 Selenium-73m ²	D, see ⁷⁰ Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
	W, see ⁷⁰ Se	3E+4	1E+5	6E-5	2E-7	-	-
34 Selenium-73	D, see ⁷⁰ Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
	W, see ⁷⁰ Se	-	2E+4	7E-6	2E-8	-	-
34 Selenium-75	D, see ⁷⁰ Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
	W, see ⁷⁰ Se	-	6E+2	3E-7	8E-10	-	-
34 Selenium-79	D, see ⁷⁰ Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
	W, see ⁷⁰ Se	-	6E+2	2E-7	8E-10	-	-
34 Selenium-81m ²	D, see ⁷⁰ Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, see ⁷⁰ Se	2E+4	7E+4	3E-5	1E-7	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
34	Selenium-81 ²	D, see ⁷⁰ Se	6E+4	2E+5	9E-5	3E-7	-	-
		St wall	(8E+4)	-	-	-	1E-3	1E-2
		W, see ⁷⁰ Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83 ²	D, see ⁷⁰ Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ⁷⁰ Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m ²	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
		St wall	(2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Se, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-
35	Bromine-74 ²	D, see ^{74m} Br	2E+4	7E+4	3E-5	1E-7	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m} Br	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75 ²	D, see ^{74m} Br	3E+4	5E+4	2E-5	7E-8	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m} Br	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see ^{74m} Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m} Br	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see ^{74m} Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m} Br	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see ^{74m} Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m} Br	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80 ²	D, see ^{74m} Br	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(9E+4)	-	-	-	1E-3	1E-2
		W, see ^{74m} Br	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see ^{74m} Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m} Br	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see ^{74m} Br	5E+4	6E+4	3E-5	9E-8	-	-
		St wall	(7E+4)	-	-	-	9E-4	9E-3
		W, see ^{74m} Br	-	6E+4	3E-5	9E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)
		Oral Ingestion	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
			ALI (μCi)	ALI (μCi)			
35 Bromine-84 ²	D, see ^{74m} Br	2E+4	6E+4	2E-5	8E-8	-	-
		St wall (3E+4)	-	-	-	4E-4	4E-3
	W, see ^{74m} Br	-	6E+4	3E-5	9E-8	-	-
36 Krypton-74 ²	Submersion ¹	-	-	3E-6	1E-8	-	-
36 Krypton-76	Submersion ¹	-	-	9E-6	4E-8	-	-
36 Krypton-77 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
36 Krypton-79	Submersion ¹	-	-	2E-5	7E-8	-	-
36 Krypton-81	Submersion ¹	-	-	7E-4	3E-6	-	-
36 Krypton-83m ²	Submersion ¹	-	-	1E-2	5E-5	-	-
36 Krypton-85m	Submersion ¹	-	-	2E-5	1E-7	-	-
36 Krypton-85	Submersion ¹	-	-	1E-4	7E-7	-	-
36 Krypton-87 ²	Submersion ¹	-	-	5E-6	2E-8	-	-
36 Krypton-88	Submersion ¹	-	-	2E-6	9E-9	-	-
37 Rubidium-79 ²	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
		St wall (6E+4)	-	-	-	8E-4	8E-3
37 Rubidium-81m ²	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
		St wall (3E+5)	-	-	-	4E-3	4E-2
37 Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37 Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37 Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37 Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37 Rubidium-88 ²	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
		St wall (3E+4)	-	-	-	4E-4	4E-3
37 Rubidium-89 ²	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-
		St wall (6E+4)	-	-	-	9E-4	9E-3
38 Strontium-80 ²	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and SrTiO	-	1E+4	5E-6	2E-8	-
38 Strontium-81 ²	D, see ⁸⁰ Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ⁸⁰ Sr	2E+4	8E+4	3E-5	1E-7	-
38 Strontium-82	D, see ⁸⁰ Sr	3E+2	4E+2	2E-7	6E-10	-	-
		LLI wall (2E+2)	-	-	-	3E-6	3E-5
	Y, see ⁸⁰ Sr	2E+2	9E+1	4E-8	1E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
38	Strontium-83	D, see ⁸⁰ Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ⁸⁰ Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m ²	D, see ⁸⁰ Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ⁸⁰ Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see ⁸⁰ Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ⁸⁰ Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see ⁸⁰ Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ⁸⁰ Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see ⁸⁰ Sr	6E+2	8E+2	4E-7	1E-9	-	-
		LLI wall	(6E+2)	-	-	-	8E-6	8E-5
		Y, see ⁸⁰ Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see ⁸⁰ Sr	3E+1	2E+1	8E-9	-	-	-
		Bone surf	(4E+1)	(2E+1)	-	3E-11	5E-7	5E-6
		Y, see ⁸⁰ Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see ⁸⁰ Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ⁸⁰ Sr	-	4E+3	1E-6	5E-9	-	-
38	Strontium-92	D, see ⁸⁰ Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ⁸⁰ Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m ²	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see ^{86m} Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m} Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see ^{86m} Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m} Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see ^{86m} Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m} Y	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see ^{86m} Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m} Y	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see ^{86m} Y	4E+2	7E+2	3E-7	9E-10	-	-
		LLI wall	(5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{86m} Y	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m ²	W, see ^{86m} Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m} Y	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see ^{86m} Y	5E+2	2E+2	7E-8	2E-10	-	-
		LLI wall	(6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{86m} Y	-	1E+2	5E-8	2E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
39 Yttrium-92	W, see ^{86m} Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	Y, see ^{86m} Y	-	8E+3	3E-6	1E-8	-	-
39 Yttrium-93	W, see ^{86m} Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	Y, see ^{86m} Y	-	2E+3	1E-6	3E-9	-	-
39 Yttrium-94 ²	W, see ^{86m} Y	2E+4 St wall	8E+4	3E-5	1E-7	-	-
		(3E+4)	-	-	-	4E-4	4E-3
39 Yttrium-95 ²	Y, see ^{86m} Y	-	8E+4	3E-5	1E-7	-	-
	W, see ^{86m} Y	4E+4 St wall	2E+5	6E-5	2E-7	-	-
		(5E+4)	-	-	-	7E-4	7E-3
40 Zirconium-86	Y, see ^{86m} Y	-	1E+5	6E-5	2E-7	-	-
	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
	W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
	Y, carbide	-	2E+3	1E-6	3E-9	-	-
40 Zirconium-88	D, see ⁸⁶ Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
	W, see ⁸⁶ Zr	-	5E+2	2E-7	7E-10	-	-
	Y, see ⁸⁶ Zr	-	3E+2	1E-7	4E-10	-	-
40 Zirconium-89	D, see ⁸⁶ Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see ⁸⁶ Zr	-	2E+3	1E-6	3E-9	-	-
	Y, see ⁸⁶ Zr	-	2E+3	1E-6	3E-9	-	-
40 Zirconium-93	D, see ⁸⁶ Zr	1E+3 Bone surf	6E+0 Bone surf	3E-9	-	-	-
		(3E+3)	(2E+1)	-	2E-11	4E-5	4E-4
	W, see ⁸⁶ Zr	-	2E+1 Bone surf	1E-8	-	-	-
		-	(6E+1)	-	9E-11	-	-
	Y, see ⁸⁶ Zr	-	6E+1 Bone surf	2E-8	-	-	-
		-	(7E+1)	-	9E-11	-	-
40 Zirconium-95	D, see ⁸⁶ Zr	1E+3	1E+2 Bone surf	5E-8	-	2E-5	2E-4
		-	(3E+2)	-	4E-10	-	-
	W, see ⁸⁶ Zr	-	4E+2	2E-7	5E-10	-	-
	Y, see ⁸⁶ Zr	-	3E+2	1E-7	4E-10	-	-
40 Zirconium-97	D, see ⁸⁶ Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
	W, see ⁸⁶ Zr	-	1E+3	6E-7	2E-9	-	-
	Y, see ⁸⁶ Zr	-	1E+3	5E-7	2E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
41	Niobium-88 ²	W, all compounds except those given for Y	5E+4 St wall (7E+4)	2E+5	9E-5	3E-7	-	-
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89 ² (66 min)	W, see ⁸⁸ Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ⁸⁸ Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89 (122 min)	W, see ⁸⁸ Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ⁸⁸ Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see ⁸⁸ Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ⁸⁸ Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see ⁸⁸ Nb	9E+3	2E+3	8E-7	3E-9	-	-
		LLI wall	(1E+4)	-	-	-	2E-4	2E-3
		Y, see ⁸⁸ Nb	-	2E+2	7E-8	2E-10	-	-
41	Niobium-94	W, see ⁸⁸ Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ⁸⁸ Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see ⁸⁸ Nb	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall	(2E+3)	-	-	-	3E-5	3E-4
		Y, see ⁸⁸ Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see ⁸⁸ Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ⁸⁸ Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see ⁸⁸ Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ⁸⁸ Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-97 ²	W, see ⁸⁸ Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ⁸⁸ Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98 ²	W, see ⁸⁸ Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ⁸⁸ Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see ⁹⁰ Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ⁹⁰ Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see ⁹⁰ Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ⁹⁰ Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see ⁹⁰ Mo	2E+3	3E+3	1E-6	4E-9	-	-
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4
		Y, see ⁹⁰ Mo	1E+3	1E+3	6E-7	2E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	ALI (μCi)				DAC (μCi/ml)
42	Molybdenum-101 ²	D, see ⁹⁰ Mo	4E+4 St wall (5E+4)	1E+5	6E-5	2E-7	-	-
		Y, see ⁹⁰ Mo	-	1E+5	6E-5	2E-7	-	7E-4
43	Technetium-93m ²	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see ^{93m} Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m} Tc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m ²	D, see ^{93m} Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m} Tc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see ^{93m} Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m} Tc	-	2E+4	1E-5	3E-8	-	-
43	Technetium-95m	D, see ^{93m} Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m} Tc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see ^{93m} Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m} Tc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m ²	D, see ^{93m} Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m} Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see ^{93m} Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m} Tc	-	2E+3	9E-7	3E-9	-	-
43	Technetium-97m	D, see ^{93m} Tc	5E+3 St wall (7E+3)	7E+3	3E-6	-	6E-5	6E-4
		W, see ^{93m} Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m} Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m} Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m} Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m} Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m} Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m} Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m} Tc	4E+3 St wall (6E+3)	5E+3	2E-6	-	6E-5	6E-4
		W, see ^{93m} Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101 ²	D, see ^{93m} Tc	9E+4 St wall (1E+5)	3E+5	1E-4	5E-7	-	-
		W, see ^{93m} Tc	-	4E+5	2E-4	5E-7	2E-3	2E-2

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
43	Technetium-104 ²	D, see ^{93m} Tc	2E+4	7E+4	3E-5	1E-7	-	-
		St wall	(3E+4)	-	-	-	4E-4	4E-3
		W, see ^{93m} Tc	-	9E+4	4E-5	1E-7	-	-
44	Ruthenium-94 ²	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44	Ruthenium-97	D, see ⁹⁴ Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see ⁹⁴ Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ⁹⁴ Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see ⁹⁴ Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see ⁹⁴ Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ⁹⁴ Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see ⁹⁴ Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see ⁹⁴ Ru	2E+2	9E+1	4E-8	1E-10	-	-
		LLI wall	(2E+2)	-	-	-	3E-6	3E-5
		W, see ⁹⁴ Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see ⁹⁴ Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see ^{99m} Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m} Rh	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{99m} Rh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see ^{99m} Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m} Rh	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{99m} Rh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see ^{99m} Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m} Rh	-	8E+3	4E-6	1E-8	-	-
		Y, see ^{99m} Rh	-	8E+3	3E-6	1E-8	-	-
45	Rhodium-101	D, see ^{99m} Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m} Rh	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{99m} Rh	-	2E+2	6E-8	2E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
45	Rhodium-102m	D, see ^{99m} Rh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall					
			(1E+3)	-	-	-	2E-5	2E-4
		W, see ^{99m} Rh	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{99m} Rh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see ^{99m} Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m} Rh	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{99m} Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m ²	D, see ^{99m} Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m} Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m} Rh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see ^{99m} Rh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall					
			(4E+3)	-	-	-	5E-5	5E-4
		W, see ^{99m} Rh	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{99m} Rh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see ^{99m} Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m} Rh	-	4E+4	2E-5	5E-8	-	-
		Y, see ^{99m} Rh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107 ²	D, see ^{99m} Rh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall					
			(9E+4)	-	-	-	1E-3	1E-2
		W, see ^{99m} Rh	-	3E+5	1E-4	4E-7	-	-
		Y, see ^{99m} Rh	-	3E+5	1E-4	3E-7	-	-
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see ¹⁰⁰ Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ¹⁰⁰ Pd	-	3E+4	1E-5	5E-8	-	-
		Y, see ¹⁰⁰ Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see ¹⁰⁰ Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall					
			(7E+3)	-	-	-	1E-4	1E-3
		W, see ¹⁰⁰ Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see ¹⁰⁰ Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see ¹⁰⁰ Pd	3E+4	2E+4	9E-6	-	-	-
			LLI wall Kidneys					
			(4E+4)	(2E+4)	-	3E-8	5E-4	5E-3
		W, see ¹⁰⁰ Pd	-	7E+3	3E-6	1E-8	-	-
		Y, see ¹⁰⁰ Pd	-	4E+2	2E-7	6E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
46 Palladium-109	D, see ¹⁰⁰ Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
	W, see ¹⁰⁰ Pd	-	5E+3	2E-6	8E-9	-	-
	Y, see ¹⁰⁰ Pd	-	5E+3	2E-6	6E-9	-	-
47 Silver-102 ²	D, all compounds except those given for W and Y	5E+4 St wall	2E+5	8E-5	2E-7	-	-
		(6E+4)	-	-	-	9E-4	9E-3
	W, nitrates and sulfides	-	2E+5	9E-5	3E-7	-	-
	Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47 Silver-103 ²	D, see ¹⁰² Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
	W, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
	Y, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
47 Silver-104m ²	D, see ¹⁰² Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
	W, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
	Y, see ¹⁰² Ag	-	1E+5	5E-5	2E-7	-	-
47 Silver-104 ²	D, see ¹⁰² Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
	W, see ¹⁰² Ag	-	1E+5	6E-5	2E-7	-	-
	Y, see ¹⁰² Ag	-	1E+5	6E-5	2E-7	-	-
47 Silver-105	D, see ¹⁰² Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
	W, see ¹⁰² Ag	-	2E+3	7E-7	2E-9	-	-
	Y, see ¹⁰² Ag	-	2E+3	7E-7	2E-9	-	-
47 Silver-106m	D, see ¹⁰² Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
	W, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
	Y, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
47 Silver-106 ²	D, see ¹⁰² Ag	6E+4 St wall	2E+5	8E-5	3E-7	-	-
		(6E+4)	-	-	-	9E-4	9E-3
	W, see ¹⁰² Ag	-	2E+5	9E-5	3E-7	-	-
	Y, see ¹⁰² Ag	-	2E+5	8E-5	3E-7	-	-
47 Silver-108m	D, see ¹⁰² Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
	W, see ¹⁰² Ag	-	3E+2	1E-7	4E-10	-	-
	Y, see ¹⁰² Ag	-	2E+1	1E-8	3E-11	-	-
47 Silver-110m	D, see ¹⁰² Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
	W, see ¹⁰² Ag	-	2E+2	8E-8	3E-10	-	-
	Y, see ¹⁰² Ag	-	9E+1	4E-8	1E-10	-	-
47 Silver-111	D, see ¹⁰² Ag	9E+2 LLI wall	2E+3 Liver	6E-7	-	-	-
		(1E+3)	(2E+3)	-	2E-9	2E-5	2E-4
	W, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-
	Y, see ¹⁰² Ag	-	9E+2	4E-7	1E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
47 Silver-112	D, see ¹⁰² Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ¹⁰² Ag	-	1E+4	4E-6	1E-8	-	-
	Y, see ¹⁰² Ag	-	9E+3	4E-6	1E-8	-	-
47 Silver-115 ²	D, see ¹⁰² Ag	3E+4 St wall	9E+4	4E-5	1E-7	-	-
		(3E+4)	-	-	-	4E-4	4E-3
	W, see ¹⁰² Ag	-	9E+4	4E-5	1E-7	-	-
48 Cadmium-104 ²	Y, see ¹⁰² Ag	-	8E+4	3E-5	1E-7	-	-
	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
48 Cadmium-107	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
	D, see ¹⁰⁴ Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
	W, see ¹⁰⁴ Cd	-	6E+4	2E-5	8E-8	-	-
48 Cadmium-109	Y, see ¹⁰⁴ Cd	-	5E+4	2E-5	7E-8	-	-
	D, see ¹⁰⁴ Cd	3E+2	4E+1	1E-8	-	-	-
		Kidneys	Kidneys				
48 Cadmium-113m		(4E+2)	(5E+1)	-	7E-11	6E-6	6E-5
	W, see ¹⁰⁴ Cd	-	1E+2	5E-8	-	-	-
		-	(1E+2)	-	2E-10	-	-
48 Cadmium-113	Y, see ¹⁰⁴ Cd	-	1E+2	5E-8	2E-10	-	-
	D, see ¹⁰⁴ Cd	2E+1	2E+0	1E-9	-	-	-
		Kidneys	Kidneys				
48 Cadmium-115m		(4E+1)	(4E+0)	-	5E-12	5E-7	5E-6
	W, see ¹⁰⁴ Cd	-	8E+0	4E-9	-	-	-
		-	(1E+1)	-	2E-11	-	-
48 Cadmium-113	Y, see ¹⁰⁴ Cd	-	1E+1	5E-9	2E-11	-	-
	D, see ¹⁰⁴ Cd	2E+1	2E+0	9E-10	-	-	-
		Kidneys	Kidneys				
48 Cadmium-115m		(3E+1)	(3E+0)	-	5E-12	4E-7	4E-6
	W, see ¹⁰⁴ Cd	-	8E+0	3E-9	-	-	-
		-	(1E+1)	-	2E-11	-	-
48 Cadmium-115m	Y, see ¹⁰⁴ Cd	-	1E+1	6E-9	2E-11	-	-
	D, see ¹⁰⁴ Cd	3E+2	5E+1	2E-8	-	4E-6	4E-5
		-	(8E+1)	-	1E-10	-	-
48 Cadmium-115m	W, see ¹⁰⁴ Cd	-	1E+2	5E-8	2E-10	-	-
	Y, see ¹⁰⁴ Cd	-	1E+2	6E-8	2E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)		
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)			
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)					
48	Cadmium-115	D, see ¹⁰⁴ Cd	9E+2	1E+3	6E-7	2E-9	-	-	
			LLI wall	(1E+3)	-	-	-	1E-5	1E-4
			W, see ¹⁰⁴ Cd	-	1E+3	5E-7	2E-9	-	-
			Y, see ¹⁰⁴ Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see ¹⁰⁴ Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4	
			W, see ¹⁰⁴ Cd	-	2E+4	7E-6	2E-8	-	-
			Y, see ¹⁰⁴ Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see ¹⁰⁴ Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4	
			W, see ¹⁰⁴ Cd	-	2E+4	7E-6	2E-8	-	-
			Y, see ¹⁰⁴ Cd	-	1E+4	6E-6	2E-8	-	-
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3	
			W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110 ² (69.1 min)	D, see ¹⁰⁹ In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3	
			W, see ¹⁰⁹ In	-	6E+4	2E-5	8E-8	-	-
49	Indium-110 (4.9 h)	D, see ¹⁰⁹ In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4	
			W, see ¹⁰⁹ In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see ¹⁰⁹ In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4	
			W, see ¹⁰⁹ In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112 ²	D, see ¹⁰⁹ In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2	
			W, see ¹⁰⁹ In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m ²	D, see ¹⁰⁹ In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3	
			W, see ¹⁰⁹ In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see ¹⁰⁹ In	3E+2	6E+1	3E-8	9E-11	-	-	
			LLI wall	(4E+2)	-	-	-	5E-6	5E-5
			W, see ¹⁰⁹ In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see ¹⁰⁹ In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3	
			W, see ¹⁰⁹ In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see ¹⁰⁹ In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6	
			W, see ¹⁰⁹ In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m ²	D, see ¹⁰⁹ In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3	
			W, see ¹⁰⁹ In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m ²	D, see ¹⁰⁹ In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3	
			W, see ¹⁰⁹ In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117 ²	D, see ¹⁰⁹ In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3	
			W, see ¹⁰⁹ In	-	2E+5	9E-5	3E-7	-	-
49	Indium-119m ²	D, see ¹⁰⁹ In	4E+4	1E+5	5E-5	2E-7	-	-	
			St wall	(5E+4)	-	-	-	7E-4	7E-3
			W, see ¹⁰⁹ In	-	1E+5	6E-5	2E-7	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
50 Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50 Tin-111 ²	D, see ¹¹⁰ Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
	W, see ¹¹⁰ Sn	-	3E+5	1E-4	4E-7	-	-
50 Tin-113	D, see ¹¹⁰ Sn	2E+3	1E+3	5E-7	2E-9	-	-
	LLI wall	(2E+3)	-	-	-	3E-5	3E-4
	W, see ¹¹⁰ Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-117m	D, see ¹¹⁰ Sn	2E+3	1E+3	5E-7	-	-	-
	LLI wall	(2E+3)	(2E+3)	-	3E-9	3E-5	3E-4
	W, see ¹¹⁰ Sn	-	1E+3	6E-7	2E-9	-	-
50 Tin-119m	D, see ¹¹⁰ Sn	3E+3	2E+3	1E-6	3E-9	-	-
	LLI wall	(4E+3)	-	-	-	6E-5	6E-4
	W, see ¹¹⁰ Sn	-	1E+3	4E-7	1E-9	-	-
50 Tin-121m	D, see ¹¹⁰ Sn	3E+3	9E+2	4E-7	1E-9	-	-
	LLI wall	(4E+3)	-	-	-	5E-5	5E-4
	W, see ¹¹⁰ Sn	-	5E+2	2E-7	8E-10	-	-
50 Tin-121	D, see ¹¹⁰ Sn	6E+3	2E+4	6E-6	2E-8	-	-
	LLI wall	(6E+3)	-	-	-	8E-5	8E-4
	W, see ¹¹⁰ Sn	-	1E+4	5E-6	2E-8	-	-
50 Tin-123m ²	D, see ¹¹⁰ Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
	W, see ¹¹⁰ Sn	-	1E+5	6E-5	2E-7	-	-
50 Tin-123	D, see ¹¹⁰ Sn	5E+2	6E+2	3E-7	9E-10	-	-
	LLI wall	(6E+2)	-	-	-	9E-6	9E-5
	W, see ¹¹⁰ Sn	-	2E+2	7E-8	2E-10	-	-
50 Tin-125	D, see ¹¹⁰ Sn	4E+2	9E+2	4E-7	1E-9	-	-
	LLI wall	(5E+2)	-	-	-	6E-6	6E-5
	W, see ¹¹⁰ Sn	-	4E+2	1E-7	5E-10	-	-
50 Tin-126	D, see ¹¹⁰ Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
	W, see ¹¹⁰ Sn	-	7E+1	3E-8	9E-11	-	-
50 Tin-127	D, see ¹¹⁰ Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	W, see ¹¹⁰ Sn	-	2E+4	8E-6	3E-8	-	-
50 Tin-128 ²	D, see ¹¹⁰ Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, see ¹¹⁰ Sn	-	4E+4	1E-5	5E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
51	Antimony-115 ²	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m ²	D, see ¹¹⁵ Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ¹¹⁵ Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116 ²	D, see ¹¹⁵ Sb	7E+4	3E+5	1E-4	4E-7	-	-
		St wall	(9E+4)	-	-	-	1E-3	1E-2
		W, see ¹¹⁵ Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see ¹¹⁵ Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ¹¹⁵ Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see ¹¹⁵ Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ¹¹⁵ Sb	5E+3	2E+4	9E-6	3E-8	-	-
51	Antimony-119	D, see ¹¹⁵ Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ¹¹⁵ Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120 ² (16 min)	D, see ¹¹⁵ Sb	1E+5	4E+5	2E-4	6E-7	-	-
		St wall	(2E+5)	-	-	-	2E-3	2E-2
		W, see ¹¹⁵ Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see ¹¹⁵ Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ¹¹⁵ Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	Antimony-122	D, see ¹¹⁵ Sb	8E+2	2E+3	1E-6	3E-9	-	-
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4
		W, see ¹¹⁵ Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m ²	D, see ¹¹⁵ Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ¹¹⁵ Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see ¹¹⁵ Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ¹¹⁵ Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see ¹¹⁵ Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ¹¹⁵ Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m ²	D, see ¹¹⁵ Sb	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(7E+4)	-	-	-	9E-4	9E-3
		W, see ¹¹⁵ Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see ¹¹⁵ Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ¹¹⁵ Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see ¹¹⁵ Sb	8E+2	2E+3	9E-7	3E-9	-	-
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4
		W, see ¹¹⁵ Sb	7E+2	9E+2	4E-7	1E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
51	Antimony-128 ² (10.4 min)	D, see ¹¹⁵ Sb	8E+4	4E+5	2E-4	5E-7	-	-
		St wall	(1E+5)	-	-	-	1E-3	1E-2
		W, see ¹¹⁵ Sb	-	4E+5	2E-4	6E-7	-	-
51	Antimony-128 (9.01 h)	D, see ¹¹⁵ Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ¹¹⁵ Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ¹¹⁵ Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ¹¹⁵ Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130 ²	D, see ¹¹⁵ Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ¹¹⁵ Sb	-	8E+4	3E-5	1E-7	-	-
51	Antimony-131 ²	D, see ¹¹⁵ Sb	1E+4 Thyroid	2E+4 Thyroid	1E-5	-	-	-
			(2E+4)	(4E+4)	-	6E-8	2E-4	2E-3
		W, see ¹¹⁵ Sb	-	2E+4 Thyroid	1E-5	-	-	-
			-	(4E+4)	-	6E-8	-	-
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see ¹¹⁶ Te	5E+2 Bone surf	2E+2 Bone surf	8E-8	-	-	-
			(7E+2)	(4E+2)	-	5E-10	1E-5	1E-4
		W, see ¹¹⁶ Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see ¹¹⁶ Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ¹¹⁶ Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see ¹¹⁶ Te	6E+2 Bone surf	2E+2 Bone surf	9E-8	-	-	-
			(1E+3)	(5E+2)	-	8E-10	1E-5	1E-4
		W, see ¹¹⁶ Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see ¹¹⁶ Te	5E+2 Bone surf	2E+2 Bone surf	8E-8	-	-	-
			(1E+3)	(5E+2)	-	7E-10	2E-5	2E-4
		W, see ¹¹⁶ Te	-	4E+2 Bone surf	2E-7	-	-	-
			-	(1E+3)	-	2E-9	-	-
52	Tellurium-125m	D, see ¹¹⁶ Te	1E+3 Bone surf	4E+2 Bone surf	2E-7	-	-	-
			(1E+3)	(1E+3)	-	1E-9	2E-5	2E-4
		W, see ¹¹⁶ Te	-	7E+2	3E-7	1E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC ($\mu\text{Ci/ml}$)		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
				Bone surf				
			-	(4E+2)	-	6E-10	-	-
		W, see ^{116}Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129 ²	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ^{116}Te	3E+2	4E+2	2E-7	-	-	-
			Thyroid	Thyroid				
			(6E+2)	(1E+3)	-	2E-9	8E-6	8E-5
		W, see ^{116}Te	-	4E+2	2E-7	-	-	-
			Thyroid					
			-	(9E+2)	-	1E-9	-	-
52	Tellurium-131 ²	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid	Thyroid				
			(6E+3)	(1E+4)	-	2E-8	8E-5	8E-4
		W, see ^{116}Te	-	5E+3	2E-6	-	-	-
			Thyroid					
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see ^{116}Te	2E+2	2E+2	9E-8	-	-	-
			Thyroid	Thyroid				
			(7E+2)	(8E+2)	-	1E-9	9E-6	9E-5
		W, see ^{116}Te	-	2E+2	9E-8	-	-	-
			Thyroid					
			-	(6E+2)	-	9E-10	-	-
52	Tellurium-133m ²	D, see ^{116}Te	3E+3	5E+3	2E-6	-	-	-
			Thyroid	Thyroid				
			(6E+3)	(1E+4)	-	2E-8	9E-5	9E-4
		W, see ^{116}Te	-	5E+3	2E-6	-	-	-
			Thyroid					
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-133 ²	D, see ^{116}Te	1E+4	2E+4	9E-6	-	-	-
			Thyroid	Thyroid				
			(3E+4)	(6E+4)	-	8E-8	4E-4	4E-3
		W, see ^{116}Te	-	2E+4	9E-6	-	-	-
			Thyroid					
			-	(6E+4)	-	8E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
52	Tellurium-134 ²	D, see ¹¹⁶ Te	2E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (5E+4)	-	7E-8	3E-4	3E-3
		W, see ¹¹⁶ Te	-	2E+4 Thyroid (5E+4)	1E-5	-	-	-
			-	(5E+4)	-	7E-8	-	-
53	Iodine-120m ²	D, all compounds	1E+4	2E+4	9E-6	3E-8	-	-
			Thyroid (1E+4)	-	-	-	2E-4	2E-3
53	Iodine-120 ²	D, all compounds	4E+3	9E+3	4E-6	-	-	-
			Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-121	D, all compounds	1E+4	2E+4	8E-6	-	-	-
			Thyroid (3E+4)	Thyroid (5E+4)	-	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3	6E+3	3E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1	8E+1	3E-8	-	-	-
			Thyroid (2E+2)	Thyroid (3E+2)	-	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1	6E+1	3E-8	-	-	-
			Thyroid (1E+2)	Thyroid (2E+2)	-	3E-10	2E-6	2E-5
53	Iodine-126	D, all compounds	2E+1	4E+1	1E-8	-	-	-
			Thyroid (7E+1)	Thyroid (1E+2)	-	2E-10	1E-6	1E-5
53	Iodine-128 ²	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
53	Iodine-129	D, all compounds	5E+0	9E+0	4E-9	-	-	-
			Thyroid (2E+1)	Thyroid (3E+1)	-	4E-11	2E-7	2E-6
53	Iodine-130	D, all compounds	4E+2	7E+2	3E-7	-	-	-
			Thyroid (1E+3)	Thyroid (2E+3)	-	3E-9	2E-5	2E-4
53	Iodine-131	D, all compounds	3E+1	5E+1	2E-8	-	-	-
			Thyroid (9E+1)	Thyroid (2E+2)	-	2E-10	1E-6	1E-5
53	Iodine-132m ²	D, all compounds	4E+3	8E+3	4E-6	-	-	-
			Thyroid (1E+4)	Thyroid (2E+4)	-	3E-8	1E-4	1E-3

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)	
53 Iodine-132	D, all compounds	4E+3	8E+3	3E-6	-	-	-
		Thyroid (9E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3
53 Iodine-133	D, all compounds	1E+2	3E+2	1E-7	-	-	-
		Thyroid (5E+2)	Thyroid (9E+2)	-	1E-9	7E-6	7E-5
53 Iodine-134 ²	D, all compounds	2E+4	5E+4	2E-5	6E-8	-	-
		Thyroid (3E+4)	-	-	-	4E-4	4E-3
53 Iodine-135	D, all compounds	8E+2	2E+3	7E-7	-	-	-
		Thyroid (3E+3)	Thyroid (4E+3)	-	6E-9	3E-5	3E-4
54 Xenon-120 ²	Submersion ¹	-	-	1E-5	4E-8	-	-
54 Xenon-121 ²	Submersion ¹	-	-	2E-6	1E-8	-	-
54 Xenon-122	Submersion ¹	-	-	7E-5	3E-7	-	-
54 Xenon-123	Submersion ¹	-	-	6E-6	3E-8	-	-
54 Xenon-125	Submersion ¹	-	-	2E-5	7E-8	-	-
54 Xenon-127	Submersion ¹	-	-	1E-5	6E-8	-	-
54 Xenon-129m	Submersion ¹	-	-	2E-4	9E-7	-	-
54 Xenon-131m	Submersion ¹	-	-	4E-4	2E-6	-	-
54 Xenon-133m	Submersion ¹	-	-	1E-4	6E-7	-	-
54 Xenon-133	Submersion ¹	-	-	1E-4	5E-7	-	-
54 Xenon-135m ²	Submersion ¹	-	-	9E-6	4E-8	-	-
54 Xenon-135	Submersion ¹	-	-	1E-5	7E-8	-	-
54 Xenon-138 ²	Submersion ¹	-	-	4E-6	2E-8	-	-
55 Cesium-125 ²	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
		St wall (9E+4)	-	-	-	1E-3	1E-2
55 Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55 Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55 Cesium-130 ²	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
		St wall (1E+5)	-	-	-	1E-3	1E-2
55 Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55 Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55 Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
		St wall (1E+5)	-	-	-	2E-3	2E-2
55 Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55 Cesium-135m ²	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55 Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55 Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138 ²	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall					
			(3E+4)	-	-	-	4E-4	4E-3
56	Barium-126 ²	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m ²	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall					
			(5E+5)	-	-	-	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall					
			(3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139 ²	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall					
			(6E+2)	-	-	-	8E-6	8E-5
56	Barium-141 ²	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142 ²	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131 ²	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see ¹³¹ La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ¹³¹ La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see ¹³¹ La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ¹³¹ La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see ¹³¹ La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			Liver					
			-	(7E+1)	-	1E-10	-	-
		W, see ¹³¹ La	-	3E+2	1E-7	-	-	-
			Liver					
			-	(3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see ¹³¹ La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ¹³¹ La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see ¹³¹ La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ¹³¹ La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see ¹³¹ La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ¹³¹ La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-142 ²	D, see ¹³¹ La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ¹³¹ La	-	3E+4	1E-5	5E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
57	Lanthanum-143 ²	D, see ¹³¹ La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ¹³¹ La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ¹³⁴ Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ¹³⁴ Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ¹³⁴ Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ¹³⁴ Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see ¹³⁴ Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ¹³⁴ Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ¹³⁴ Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ¹³⁴ Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ¹³⁴ Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ¹³⁴ Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ¹³⁴ Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹³⁴ Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ¹³⁴ Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see ¹³⁴ Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136 ²	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-
59	Praseodymium-137 ²	W, see ¹³⁶ Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ¹³⁶ Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see ¹³⁶ Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ¹³⁶ Pr	-	4E+4	2E-5	6E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
59	Praseodymium-139	W, see ¹³⁶ Pr Y, see ¹³⁶ Pr	4E+4 -	1E+5 1E+5	5E-5 5E-5	2E-7 2E-7	6E-4 -	6E-3 -
59	Praseodymium-142m ²	W, see ¹³⁶ Pr Y, see ¹³⁶ Pr	8E+4 -	2E+5 1E+5	7E-5 6E-5	2E-7 2E-7	1E-3 -	1E-2 -
59	Praseodymium-142	W, see ¹³⁶ Pr Y, see ¹³⁶ Pr	1E+3 -	2E+3 2E+3	9E-7 8E-7	3E-9 3E-9	1E-5 -	1E-4 -
59	Praseodymium-143	W, see ¹³⁶ Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹³⁶ Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144 ²	W, see ¹³⁶ Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ¹³⁶ Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see ¹³⁶ Pr Y, see ¹³⁶ Pr	3E+3 -	9E+3 8E+3	4E-6 3E-6	1E-8 1E-8	4E-5 -	4E-4 -
59	Praseodymium-147 ²	W, see ¹³⁶ Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see ¹³⁶ Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136 ²	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	2E+3 -	6E+3 5E+3	3E-6 2E-6	9E-9 7E-9	3E-5 -	3E-4 -
60	Neodymium-139m	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	5E+3 -	2E+4 1E+4	7E-6 6E-6	2E-8 2E-8	7E-5 -	7E-4 -
60	Neodymium-139 ²	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	9E+4 -	3E+5 3E+5	1E-4 1E-4	5E-7 4E-7	1E-3 -	1E-2 -
60	Neodymium-141	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	2E+5 -	7E+5 6E+5	3E-4 3E-4	1E-6 9E-7	2E-3 -	2E-2 -
60	Neodymium-147	W, see ¹³⁶ Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹³⁶ Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149 ²	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	1E+4 -	3E+4 2E+4	1E-5 1E-5	4E-8 3E-8	1E-4 -	1E-3 -
60	Neodymium-151 ²	W, see ¹³⁶ Nd Y, see ¹³⁶ Nd	7E+4 -	2E+5 2E+5	8E-5 8E-5	3E-7 3E-7	9E-4 -	9E-3 -

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
61	Promethium-141 ²	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(6E+4)	-	-	-	8E-4	8E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see ¹⁴¹ Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see ¹⁴¹ Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see ¹⁴¹ Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
		Bone surf	-	(2E+2)	-	3E-10	-	-
		Y, see ¹⁴¹ Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see ¹⁴¹ Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see ¹⁴¹ Pm	4E+3	1E+2	5E-8	-	-	-
		Bone surf	(5E+3)	(2E+2)	-	3E-10	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see ¹⁴¹ Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ¹⁴¹ Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see ¹⁴¹ Pm	4E+2	5E+2	2E-7	8E-10	-	-
		LLI wall	(5E+2)	-	-	-	7E-6	7E-5
		Y, see ¹⁴¹ Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see ¹⁴¹ Pm	1E+3	2E+3	8E-7	3E-9	-	-
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see ¹⁴¹ Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ¹⁴¹ Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see ¹⁴¹ Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ¹⁴¹ Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m ²	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141 ²	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
		St wall	(6E+4)	-	-	-	8E-4	8E-3
62	Samarium-142 ²	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E-2	1E-11	-	-	-
		Bone surf		Bone surf				

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
		ALI (μCi)	ALI (μCi)	DAC ($\mu\text{Ci/ml}$)				
		(3E+1)	(6E-2)	-	9E-14	3E-7	3E-6	
62	Samarium-147	W, all compounds	2E+1 Bone surf	4E-2 Bone surf	2E-11	-	-	-
			(3E+1)	(7E-2)	-	1E-13	4E-7	4E-6
62	Samarium-151	W, all compounds	1E+4 LLI wall	1E+2 Bone surf	4E-8	-	-	-
			(1E+4)	(2E+2)	-	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3 LLI wall	3E+3	1E-6	4E-9	-	-
			(2E+3)	-	-	-	3E-5	3E-4
62	Samarium-155 ²	W, all compounds	6E+4 St wall	2E+5	9E-5	3E-7	-	-
			(8E+4)	-	-	-	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
				Bone surf				
			-	(1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158 ²	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145 ²	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	-	-
			St wall					
			(5E+4)	-	-	-	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see ¹⁴⁵ Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ¹⁴⁵ Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see ¹⁴⁵ Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ¹⁴⁵ Gd	-	4E+3	1E-6	5E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)		
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC ($\mu\text{Ci/ml}$)		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)			
64	Gadolinium-148	D, see ^{145}Gd	1E+1 Bone surf (2E+1)	8E+3 Bone surf (2E+2)	3E-12	-	-	3E-6	
		W, see ^{145}Gd	-	3E-2 Bone surf (6E-2)	1E-11	-	-	-	
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4	
		W, see ^{145}Gd	-	2E+3	1E-6	3E-9	-	-	
64	Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4	
		W, see ^{145}Gd	-	1E+3	5E-7	2E-9	-	-	
64	Gadolinium-152	D, see ^{145}Gd	2E+1 Bone surf (3E+1)	1E-2 Bone surf (2E-2)	4E-12	-	3E-14	4E-7	4E-6
		W, see ^{145}Gd	-	4E-2 Bone surf (8E-2)	2E-11	-	-	-	
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4	
		W, see ^{145}Gd	-	6E+2	2E-7	8E-10	-	-	
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4	
		W, see ^{145}Gd	-	6E+3	2E-6	8E-9	-	-	
65	Terbium-147 ²	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3	
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4	
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4	
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4	
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4	
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4	
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4	
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3	
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3	
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4	
65	Terbium-157	W, all compounds	5E+4 LLI wall (5E+4)	3E+2 Bone surf (6E+2)	1E-7	-	-	-	
						8E-10	7E-4	7E-3	

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)				
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	-	-
			LLI wall					
			(2E+3)	-	-	-	3E-5	3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	-	-
			LLI wall					
			(8E+2)	-	-	-	1E-5	1E-4
67	Holmium-155 ²	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157 ²	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159 ²	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m ²	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162 ²	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall					
			(8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m ²	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164 ²	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall					
			(2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall					
			(9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall					
			(4E+3)	-	-	-	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall					
			(E+3)	-	-	-	2E-5	2E-4
69	Thulium-162 ²	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall					
			(7E+4)	-	-	-	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall					
			(2E+3)	-	-	-	3E-5	3E-4

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)		
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC ($\mu\text{Ci/ml}$)		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)			
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-	
		LLI wall	(1E+3)	-	-	-	1E-5	1E-4	
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-	
		LLI wall	(1E+4)	Bone surf	(6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-	
		LLI wall	(8E+2)	-	-	-	1E-5	1E-4	
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4	
69	Thulium-175 ²	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-	
		St wall	(9E+4)	-	-	-	1E-3	1E-2	
70	Ytterbium-162 ²	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2	
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-	
70	Ytterbium-166	W, see ¹⁶² Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4	
		Y, see ¹⁶² Yb	-	2E+3	8E-7	3E-9	-	-	
70	Ytterbium-167 ²	W, see ¹⁶² Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2	
		Y, see ¹⁶² Yb	-	7E+5	3E-4	1E-6	-	-	
70	Ytterbium-169	W, see ¹⁶² Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4	
		Y, see ¹⁶² Yb	-	7E+2	3E-7	1E-9	-	-	
70	Ytterbium-175	W, see ¹⁶² Yb	3E+3	4E+3	1E-6	5E-9	-	-	
		LLI wall	(3E+3)	-	-	-	4E-5	4E-4	
		Y, see ¹⁶² Yb	-	3E+3	1E-6	5E-9	-	-	
70	Ytterbium-177 ²	W, see ¹⁶² Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3	
		Y, see ¹⁶² Yb	-	5E+4	2E-5	6E-8	-	-	
70	Ytterbium-178 ²	W, see ¹⁶² Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3	
		Y, see ¹⁶² Yb	-	4E+4	2E-5	5E-8	-	-	
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4	
		Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-	
71	Lutetium-170	W, see ¹⁶⁹ Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4	
		Y, see ¹⁶⁹ Lu	-	2E+3	8E-7	3E-9	-	-	
71	Lutetium-171	W, see ¹⁶⁹ Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4	
		Y, see ¹⁶⁹ Lu	-	2E+3	8E-7	3E-9	-	-	
71	Lutetium-172	W, see ¹⁶⁹ Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4	
		Y, see ¹⁶⁹ Lu	-	1E+3	5E-7	2E-9	-	-	

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
71	Lutetium-173	W, see ¹⁶⁹ Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
				Bone surf				
		Y, see ¹⁶⁹ Lu	-	(5E+2)	-	6E-10	-	-
		Y, see ¹⁶⁹ Lu	-	3E+2	1E-7	4E-10	-	-
71	Lutetium-174m	W, see ¹⁶⁹ Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall	Bone surf				
			(3E+3)	(3E+2)	-	5E-10	4E-5	4E-4
		Y, see ¹⁶⁹ Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ¹⁶⁹ Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
				Bone surf				
			-	(2E+2)	-	3E-10	-	-
		Y, see ¹⁶⁹ Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ¹⁶⁹ Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ¹⁶⁹ Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see ¹⁶⁹ Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
				Bone surf				
			-	(1E+1)	-	2E-11	-	-
		Y, see ¹⁶⁹ Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see ¹⁶⁹ Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
				Bone surf				
			-	(1E+2)	-	2E-10	-	-
		Y, see ¹⁶⁹ Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see ¹⁶⁹ Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall					
			(3E+3)	-	-	-	4E-5	4E-4
		Y, see ¹⁶⁹ Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m ²	W, see ¹⁶⁹ Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St wall					
			(6E+4)	-	-	-	8E-4	8E-3
		Y, see ¹⁶⁹ Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178 ²	W, see ¹⁶⁹ Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall					
			(4E+4)	-	-	-	6E-4	6E-3
		Y, see ¹⁶⁹ Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see ¹⁶⁹ Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ¹⁶⁹ Lu	-	2E+4	6E-6	3E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	ALI (μCi)				DAC (μCi/ml)
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see ¹⁷⁰ Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
				Bone surf				
			-	(2E+1)	-	3E-11	-	-
		W, see ¹⁷⁰ Hf	-	4E+1	2E-8	-	-	-
				Bone surf				
			-	(6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see ¹⁷⁰ Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ¹⁷⁰ Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see ¹⁷⁰ Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
				Bone surf				
			-	(1E+3)	-	1E-9	-	-
		W, see ¹⁷⁰ Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m ²	D, see ¹⁷⁰ Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ¹⁷⁰ Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ¹⁷⁰ Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
				Bone surf				
			-	(2E+0)	-	3E-12	-	-
		W, see ¹⁷⁰ Hf	-	5E+0	2E-9	-	-	-
				Bone surf				
			-	(9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see ¹⁷⁰ Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
				Bone surf				
			-	(6E+2)	-	8E-10	-	-
		W, see ¹⁷⁰ Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see ¹⁷⁰ Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ¹⁷⁰ Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see ¹⁷⁰ Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
				Bone surf				
			-	(4E+2)	-	6E-10	-	-
		W, see ¹⁷⁰ Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m ²	D, see ¹⁷⁰ Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ¹⁷⁰ Hf	-	1E+5	6E-5	2E-7	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
72	Hafnium-182	D, see ¹⁷⁰ Hf	2E+2	8E-1	3E-10	-	-	-
			Bone surf (4E+2)	Bone surf (2E+0)	-	2E-12	5E-6	5E-5
		W, see ¹⁷⁰ Hf	-	3E+0	1E-9	-	-	-
			-	Bone surf (7E+0)	-	1E-11	-	-
72	Hafnium-183 ²	D, see ¹⁷⁰ Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ¹⁷⁰ Hf	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-172 ²	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73	Tantalum-173	W, see ¹⁷² Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ¹⁷² Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174 ²	W, see ¹⁷² Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ¹⁷² Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see ¹⁷² Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ¹⁷² Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see ¹⁷² Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ¹⁷² Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see ¹⁷² Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ¹⁷² Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see ¹⁷² Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ¹⁷² Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see ¹⁷² Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ¹⁷² Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ¹⁷² Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ¹⁷² Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see ¹⁷² Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ¹⁷² Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m ²	W, see ¹⁷² Ta	2E+5	5E+5	2E-4	8E-7	-	-
		St wall	(2E+5)	-	-	-	3E-3	3E-2
		Y, see ¹⁷² Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see ¹⁷² Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ¹⁷² Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see ¹⁷² Ta	9E+2	1E+3	5E-7	2E-9	-	-
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4
		Y, see ¹⁷² Ta	-	1E+3	4E-7	1E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
73 Tantalum-184	W, see ¹⁷² Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
	Y, see ¹⁷² Ta	-	5E+3	2E-6	7E-9	-	-
73 Tantalum-185 ²	W, see ¹⁷² Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
	Y, see ¹⁷² Ta	-	6E+4	3E-5	9E-8	-	-
73 Tantalum-186 ²	W, see ¹⁷² Ta	5E+4	2E+5	1E-4	3E-7	-	-
	St wall	(7E+4)	-	-	-	1E-3	1E-2
	Y, see ¹⁷² Ta	-	2E+5	9E-5	3E-7	-	-
74 Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74 Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74 Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74 Tungsten-179 ²	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74 Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74 Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
	LLI wall	(3E+3)	-	-	-	4E-5	4E-4
74 Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74 Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
	LLI wall	(5E+2)	-	-	-	7E-6	7E-5
75 Rhenium-177 ²	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
	St wall	(1E+5)	-	-	-	2E-3	2E-2
	W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75 Rhenium-178 ²	D, see ¹⁷⁷ Re	7E+4	3E+5	1E-4	4E-7	-	-
	St wall	(1E+5)	-	-	-	1E-3	1E-2
	W, see ¹⁷⁷ Re	-	3E+5	1E-4	4E-7	-	-
75 Rhenium-181	D, see ¹⁷⁷ Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
	W, see ¹⁷⁷ Re	-	9E+3	4E-6	1E-8	-	-
75 Rhenium-182 (12.7 h)	D, see ¹⁷⁷ Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
	W, see ¹⁷⁷ Re	-	2E+4	6E-6	2E-8	-	-
75 Rhenium-182 (64.0 h)	D, see ¹⁷⁷ Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, see ¹⁷⁷ Re	-	2E+3	9E-7	3E-9	-	-
75 Rhenium-184m	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see ¹⁷⁷ Re	-	4E+2	2E-7	6E-10	-	-
75 Rhenium-184	D, see ¹⁷⁷ Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
	W, see ¹⁷⁷ Re	-	1E+3	6E-7	2E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
75	Rhenium-186m	D, see ¹⁷⁷ Re	1E+3	2E+3	7E-7	-	-	-
			St wall (2E+3)	St wall (2E+3)	-	3E-9	2E-5	2E-4
		W, see ¹⁷⁷ Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ¹⁷⁷ Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see ¹⁷⁷ Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
			St wall (9E+5)	-	1E-6	-	-	-
		W, see ¹⁷⁷ Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m ²	D, see ¹⁷⁷ Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ¹⁷⁷ Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see ¹⁷⁷ Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ¹⁷⁷ Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see ¹⁷⁷ Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ¹⁷⁷ Re	-	4E+3	2E-6	6E-9	-	-
76	Osmium-180 ²	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181 ²	D, see ¹⁸⁰ Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ¹⁸⁰ Os	-	5E+4	2E-5	6E-8	-	-
		Y, see ¹⁸⁰ Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see ¹⁸⁰ Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ¹⁸⁰ Os	-	4E+3	2E-6	6E-9	-	-
		Y, see ¹⁸⁰ Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see ¹⁸⁰ Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ¹⁸⁰ Os	-	8E+2	3E-7	1E-9	-	-
		Y, see ¹⁸⁰ Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see ¹⁸⁰ Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ¹⁸⁰ Os	-	2E+5	9E-5	3E-7	-	-
		Y, see ¹⁸⁰ Os	-	2E+5	7E-5	2E-7	-	-
76	Osmium-191m	D, see ¹⁸⁰ Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ¹⁸⁰ Os	-	2E+4	8E-6	3E-8	-	-
		Y, see ¹⁸⁰ Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see ¹⁸⁰ Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see ¹⁸⁰ Os	-	2E+3	7E-7	2E-9	-	-
		Y, see ¹⁸⁰ Os	-	1E+3	6E-7	2E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
76	Osmium-193	D, see ¹⁸⁰ Os	2E+3	5E+3	2E-6	6E-9	-	-
		LLI wall	(2E+3)	-	-	-	2E-5	2E-4
		W, see ¹⁸⁰ Os	-	3E+3	1E-6	4E-9	-	-
		Y, see ¹⁸⁰ Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see ¹⁸⁰ Os	4E+2	4E+1	2E-8	6E-11	-	-
		LLI wall	(6E+2)	-	-	-	8E-6	8E-5
		W, see ¹⁸⁰ Os	-	6E+1	2E-8	8E-11	-	-
		Y, see ¹⁸⁰ Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182 ²	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
		St wall	(4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77	Iridium-184	D, see ¹⁸² Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ¹⁸² Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see ¹⁸² Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ¹⁸² Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see ¹⁸² Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see ¹⁸² Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ¹⁸² Ir	-	6E+3	3E-6	9E-9	-	-
		Y, see ¹⁸² Ir	-	6E+3	2E-6	8E-9	-	-
77	Iridium-187	D, see ¹⁸² Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see ¹⁸² Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ¹⁸² Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see ¹⁸² Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see ¹⁸² Ir	5E+3	5E+3	2E-6	7E-9	-	-
		LLI wall	(5E+3)	-	-	-	7E-5	7E-4
		W, see ¹⁸² Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see ¹⁸² Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m ²	D, see ¹⁸² Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ¹⁸² Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see ¹⁸² Ir	-	2E+5	8E-5	3E-7	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	ALI (μCi)				DAC (μCi/ml)
77 Iridium-190	D, see ¹⁸² Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4	
	W, see ¹⁸² Ir	-	1E+3	4E-7	1E-9	-	-	
	Y, see ¹⁸² Ir	-	9E+2	4E-7	1E-9	-	-	
77 Iridium-192m	D, see ¹⁸² Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4	
	W, see ¹⁸² Ir	-	2E+2	9E-8	3E-10	-	-	
	Y, see ¹⁸² Ir	-	2E+1	6E-9	2E-11	-	-	
77 Iridium-192	D, see ¹⁸² Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4	
	W, see ¹⁸² Ir	-	4E+2	2E-7	6E-10	-	-	
	Y, see ¹⁸² Ir	-	2E+2	9E-8	3E-10	-	-	
77 Iridium-194m	D, see ¹⁸² Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5	
	W, see ¹⁸² Ir	-	2E+2	7E-8	2E-10	-	-	
	Y, see ¹⁸² Ir	-	1E+2	4E-8	1E-10	-	-	
77 Iridium-194	D, see ¹⁸² Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4	
	W, see ¹⁸² Ir	-	2E+3	9E-7	3E-9	-	-	
	Y, see ¹⁸² Ir	-	2E+3	8E-7	3E-9	-	-	
77 Iridium-195m	D, see ¹⁸² Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3	
	W, see ¹⁸² Ir	-	3E+4	1E-5	4E-8	-	-	
	Y, see ¹⁸² Ir	-	2E+4	9E-6	3E-8	-	-	
77 Iridium-195	D, see ¹⁸² Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3	
	W, see ¹⁸² Ir	-	5E+4	2E-5	7E-8	-	-	
	Y, see ¹⁸² Ir	-	4E+4	2E-5	6E-8	-	-	
78 Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3	
78 Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4	
78 Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3	
78 Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4	
78 Platinum-193m	D, all compounds		3E+3	6E+3	3E-6	8E-9	-	-
		LLI wall (3E+4)	-	-	-	-	4E-5	4E-4
78 Platinum-193	D, all compounds		4E+4	2E+4	1E-5	3E-8	-	-
		LLI wall (5E+4)	-	-	-	-	6E-4	6E-3
78 Platinum-195m	D, all compounds		2E+3	4E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	-	3E-5	3E-4
78 Platinum-197m ²	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3	
78 Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4	
78 Platinum-199 ²	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3	
78 Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4	

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)
		Oral Ingestion ALI (μCi)	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
			ALI (μCi)	DAC ($\mu\text{Ci/ml}$)			
79 Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
	Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79 Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
	Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-
79 Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
	Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79 Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
	Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79 Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
	Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79 Gold-199	D, see ^{193}Au	3E+3 LLI wall	9E+3	4E-6	1E-8	-	-
		(3E+3)	-	-	-	4E-5	4E-4
	W, see ^{193}Au	-	4E+3	2E-6	6E-9	-	-
79 Gold-200m	Y, see ^{193}Au	-	4E+3	2E-6	5E-9	-	-
	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see ^{193}Au	-	3E+3	1E-6	4E-9	-	-
79 Gold-200 ²	Y, see ^{193}Au	-	2E+4	1E-6	3E-9	-	-
	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
	W, see ^{193}Au	-	8E+4	3E-5	1E-7	-	-
79 Gold-201 ²	Y, see ^{193}Au	-	7E+4	3E-5	1E-7	-	-
	D, see ^{193}Au	7E+4 St wall	2E+5	9E-5	3E-7	-	-
		(9E+4)	-	-	-	1E-3	1E-2
80 Mercury-193m	W, see ^{193}Au	-	2E+5	1E-4	3E-7	-	-
	Y, see ^{193}Au	-	2E+5	9E-5	3E-7	-	-
	Vapor	-	8E+3	4E-6	1E-8	-	-
80 Mercury-193	Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80 Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	D, see ^{193}mHg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see ^{193}mHg	-	4E+4	2E-5	6E-8	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)
		Oral Ingestion ALI (μCi)	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)	
			ALI (μCi)	DAC ($\mu\text{Ci/ml}$)			
80 Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
	Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
	D, see ^{193m} Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
	W, see ^{193m} Hg	-	1E+2	5E-8	2E-10	-	-
80 Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
	Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
	D, see ^{193m} Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
	W, see ^{193m} Hg	-	4E+3	2E-6	5E-9	-	-
80 Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
	D, see ^{193m} Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
	W, see ^{193m} Hg	-	3E+4	1E-5	5E-8	-	-
80 Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
	Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
	D, see ^{193m} Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
	W, see ^{193m} Hg	-	5E+3	2E-6	7E-9	-	-
80 Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
	D, see ^{193m} Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
	W, see ^{193m} Hg	-	9E+3	4E-6	1E-8	-	-
80 Mercury-199m ²	Vapor	-	8E+4	3E-5	1E-7	-	-
	Organic D	6E+4	2E+5	7E-5	2E-7	-	-
		(1E+5)	-	-	-	1E-3	1E-2
	D, see ^{193m} Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
	W, see ^{193m} Hg	-	2E+5	7E-5	2E-7	-	-
80 Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
	Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
	D, see ^{193m} Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
	W, see ^{193m} Hg	-	1E+3	5E-7	2E-9	-	-
81 Thallium-194m ²	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
		(7E+4)	-	-	-	1E-3	1E-2
81 Thallium-194 ²	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
		(3E+5)	-	-	-	4E-3	4E-2
81 Thallium-195 ²	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81 Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81 Thallium-198m ²	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81 Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81 Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81 Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81 Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81 Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion	INHALATION		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
			ALI (μCi)	ALI (μCi)				DAC ($\mu\text{Ci/ml}$)
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m ²	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199 ²	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E-1 Bone surf	2E-1 Bone surf	1E-10	-	-	-
			(1E+0)	(4E-1)	-	6E-13	1E-8	1E-7
82	Lead-211 ²	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1 Bone surf	3E+1	1E-8	5E-11	-	-
			(1E+2)	-	-	-	2E-6	2E-5
82	Lead-214 ²	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200 ²	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83	Bismuth-201 ²	D, see ²⁰⁰ Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ²⁰⁰ Bi	-	4E+4	2E-5	5E-8	-	-
83	Bismuth-202 ²	D, see ²⁰⁰ Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ²⁰⁰ Bi	-	8E+4	3E-5	1E-7	-	-
83	Bismuth-203	D, see ²⁰⁰ Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see ²⁰⁰ Bi	-	6E+3	3E-6	9E-9	-	-
83	Bismuth-205	D, see ²⁰⁰ Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see ²⁰⁰ Bi	-	1E+3	5E-7	2E-9	-	-
83	Bismuth-206	D, see ²⁰⁰ Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ²⁰⁰ Bi	-	9E+2	4E-7	1E-9	-	-
83	Bismuth-207	D, see ²⁰⁰ Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ²⁰⁰ Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-210m	D, see ²⁰⁰ Bi	4E+1	5E+0	2E-9	-	-	-
		Kidneys	Kidneys					
			(6E+1)	(6E+0)	-	9E-12	8E-7	8E-6
		W, see ²⁰⁰ Bi	-	7E-1	3E-10	9E-13	-	-
83	Bismuth-210	D, see ²⁰⁰ Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
				Kidneys				
			-	(4E+2)	-	5E-10	-	-
		W, see ²⁰⁰ Bi	-	3E+1	1E-8	4E-11	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ($\mu\text{Ci/ml}$)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC ($\mu\text{Ci/ml}$)		Air ($\mu\text{Ci/ml}$)	Water ($\mu\text{Ci/ml}$)		
83	Bismuth-212 ²	D, see ²⁰⁰ Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ²⁰⁰ Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213 ²	D, see ²⁰⁰ Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ²⁰⁰ Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214 ²	D, see ²⁰⁰ Bi	2E+4	8E+2	3E-7	1E-9	-	-
		St wall	(2E+4)	-	-	-	3E-4	3E-3
		W, see ²⁰⁰ Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203 ²	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205 ²	D, see ²⁰³ Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ²⁰³ Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see ²⁰³ Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ²⁰³ Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see ²⁰³ Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ²⁰³ Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207 ²	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1	9E-9	3E-11	-	-
				(or 12 working level months)	(or 1.0 working level)			
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2	3E-8	1E-10	-	-
				(or 4 working level months)	(or 0.33 working level)			
87	Francium-222 ²	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223 ²	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	-	-
		Bone surf	(9E+0)	-	-	-	1E-7	1E-6

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	ALI (μCi)			
88 Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	-	-
		Bone surf					
		(2E+1)	-	-	-	2E-7	2E-6
88 Radium-225	W, all compounds	8E+0	7E-1	3E-10	9E-13	-	-
		Bone surf					
		(2E+1)	-	-	-	2E-7	2E-6
88 Radium-226	W, all compounds	2E+0	6E-1	3E-10	9E-13	-	-
		Bone surf					
		(5E+0)	-	-	-	6E-8	6E-7
88 Radium-227 ²	W, all compounds	2E+4	1E+4	6E-6	-	-	-
		Bone surf	Bone surf				
		(2E+4)	(2E+4)	-	3E-8	3E-4	3E-3
88 Radium-228	W, all compounds	2E+0	1E+0	5E-10	2E-12	-	-
		Bone surf					
		(4E+0)	-	-	-	6E-8	6E-7
89 Actinium-224	D, all compounds except those given for W and Y	2E+3 LLI wall	3E+1 Bone surf	1E-8	-	-	-
		(2E+3)	(4E+1)	-	5E-11	3E-5	3E-4
	W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
	Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-
89 Actinium-225	D, see ²²⁴ Ac	5E+1 LLI wall	3E-1 Bone surf	1E-10	-	-	-
		(5E+1)	(5E-1)	-	7E-13	7E-7	7E-6
	W, see ²²⁴ Ac	-	6E-1	3E-10	9E-13	-	-
	Y, see ²²⁴ Ac	-	6E-1	3E-10	9E-13	-	-
89 Actinium-226	D, see ²²⁴ Ac	1E+2 LLI wall	3E+0 Bone surf	1E-9	-	-	-
		(1E+2)	(4E+0)	-	5E-12	2E-6	2E-5
	W, see ²²⁴ Ac	-	5E+0	2E-9	7E-12	-	-
	Y, see ²²⁴ Ac	-	5E+0	2E-9	6E-12	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)	
89 Actinium-227	D, see ²²⁴ Ac	2E-1 Bone surf	4E-4 Bone surf	2E-13	-	-	-
		(4E-1)	(8E-4)	-	1E-15	5E-9	5E-8
	W, see ²²⁴ Ac	-	2E-3 Bone surf	7E-13	-	-	-
		-	(3E-3)	-	4E-15	-	-
89 Actinium-228	D, see ²²⁴ Ac	-	4E-3	2E-12	6E-15	-	-
		2E+3	9E+0 Bone surf	4E-9	-	3E-5	3E-4
	W, see ²²⁴ Ac	-	(2E+1)	-	2E-11	-	-
		-	4E+1 Bone surf	2E-8	-	-	-
90 Thorium-226 ²	W, all compounds except those given for Y	-	(6E+1)	-	8E-11	-	-
		-	4E+1	2E-8	6E-11	-	-
	Y, see ²²⁴ Ac	-	4E+1	2E-8	6E-11	-	-
90 Thorium-227	W, see ²²⁶ Th	5E+3 St wall	2E+2	6E-8	2E-10	-	-
		(5E+3)	-	-	-	7E-5	7E-4
90 Thorium-228	W, see ²²⁶ Th	-	1E+2	6E-8	2E-10	-	-
		1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
90 Thorium-229	W, see ²²⁶ Th	-	3E-1	1E-10	5E-13	-	-
		6E+0 Bone surf	1E-2 Bone surf	4E-12	-	-	-
	Y, see ²²⁶ Th	(1E+1)	(2E-2)	-	3E-14	2E-7	2E-6
90 Thorium-230	W, see ²²⁶ Th	-	2E-2	7E-12	2E-14	-	-
		6E-1 Bone surf	9E-4 Bone surf	4E-13	-	-	-
	Y, see ²²⁶ Th	(1E+0)	(2E-3)	-	3E-15	2E-8	2E-7
90 Thorium-231	W, see ²²⁶ Th	-	2E-3	1E-12	-	-	-
		-	(3E-3)	-	4E-15	-	-
	Y, see ²²⁶ Th	4E+0 Bone surf	6E-3 Bone surf	3E-12	-	-	-
90 Thorium-231	W, see ²²⁶ Th	(9E+0)	(2E-2)	-	2E-14	1E-7	1E-6
		-	2E-2	6E-12	-	-	-
	Y, see ²²⁶ Th	-	(2E-2)	-	3E-14	-	-
90 Thorium-231	W, see ²²⁶ Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		-	6E+3	3E-6	9E-9	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
90 Thorium-232	W, see ²²⁶ Th	7E-1	1E-3	5E-13	-	-	-
		Bone surf	Bone surf				
		(2E+0)	(3E-3)	-	4E-15	3E-8	3E-7
	Y, see ²²⁶ Th	-	3E-3	1E-12	-	-	-
			Bone surf				
		-	(4E-3)	-	6E-15	-	-
90 Thorium-234	W, see ²²⁶ Th	3E+2	2E+2	8E-8	3E-10	-	-
		LLI wall					
		(4E+2)	-	-	-	5E-6	5E-5
	Y, see ²²⁶ Th	-	2E+2	6E-8	2E-10	-	-
91 Protactinium-227 ²	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
	Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91 Protactinium-228	W, see ²²⁷ Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
			Bone surf				
		-	(2E+1)	-	3E-11	-	-
	Y, see ²²⁷ Pa	-	1E+1	5E-9	2E-11	-	-
91 Protactinium-230	W, see ²²⁷ Pa	6E+2	5E+0	2E-9	7E-12	-	-
		Bone surf					
		(9E+2)	-	-	-	1E-5	1E-4
	Y, see ²²⁷ Pa	-	4E+0	1E-9	5E-12	-	-
91 Protactinium-231	W, see ²²⁷ Pa	2E-1	2E-3	6E-13	-	-	-
		Bone surf	Bone surf				
		(5E-1)	(4E-3)	-	6E-15	6E-9	6E-8
	Y, see ²²⁷ Pa	-	4E-3	2E-12	-	-	-
			Bone surf				
		-	(6E-3)	-	8E-15	-	-
91 Protactinium-232	W, see ²²⁷ Pa	1E+3	2E+1	9E-9	-	2E-5	2E-4
			Bone surf				
		-	(6E+1)	-	8E-11	-	-
	Y, see ²²⁷ Pa	-	6E+1	2E-8	-	-	-
			Bone surf				
		-	(7E+1)	-	1E-10	-	-
91 Protactinium-233	W, see ²²⁷ Pa	1E+3	7E+2	3E-7	1E-9	-	-
		LLI wall					
		(2E+3)	-	-	-	E-5	2E-4
	Y, see ²²⁷ Pa	-	6E+2	2E-7	8E-10	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (µCi/ml)	
		Oral Ingestion ALI (µCi)	INHALATION ALI (µCi) DAC (µCi/ml)		Air (µCi/ml)	Water (µCi/ml)		
91	Protactinium-234	W, see ²²⁷ Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ²²⁷ Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF, UOF, UO(NO)	4E+0	4E-1	2E-10	-	-	-
		Bone surf	(6E+0)	(6E-1)	-	8E-13	8E-8	8E-7
		W, UO, UF, UCI	-	4E-1	1E-10	5E-13	-	-
		Y, UO, UO	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see ²³⁰ U	5E+3	8E+3	3E-6	1E-8	-	-
		LLI wall	(4E+3)	-	-	-	6E-5	6E-4
		W, see ²³⁰ U	-	6E+3	2E-6	8E-9	-	-
		Y, see ²³⁰ U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see ²³⁰ U	2E+0	2E-1	9E-11	-	-	-
		Bone surf	(4E+0)	(4E-1)	-	6E-13	6E-8	6E-7
		W, see ²³⁰ U	-	4E-1	2E-10	5E-13	-	-
		Y, see ²³⁰ U	-	8E-3	3E-12	1E-14	-	-
92	Uranium-233	D, see ²³⁰ U	1E+1	1E+0	5E-10	-	-	-
		Bone surf	(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	7E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234 ³	D, see ²³⁰ U	1E+1	1E+0	5E-10	-	-	-
		Bone surf	(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	7E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235 ³	D, see ²³⁰ U	1E+1	1E+0	6E-10	-	-	-
		Bone surf	(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see ²³⁰ U	1E+1	1E+0	5E-10	-	-	-
		Bone surf	(2E+1)	(2E+0)	-	3E-12	3E-7	3E-6
		W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
		Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)	
92 Uranium-237	D, see ²³⁰ U	2E+3 LLI wall (2E+3)	3E+3 -	1E-6 -	4E-9 -	- 3E-5	- 3E-4
	W, see ²³⁰ U	-	2E+3	7E-7	2E-9	-	-
	Y, see ²³⁰ U	-	2E+3	6E-7	2E-9	-	-
92 Uranium-238 ³	D, see ²³⁰ U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ²³⁰ U	-	8E-1	3E-10	1E-12	-	-
	Y, see ²³⁰ U	-	4E-2	2E-11	6E-14	-	-
92 Uranium-239 ²	D, see ²³⁰ U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
	W, see ²³⁰ U	-	2E+5	7E-5	2E-7	-	-
	Y, see ²³⁰ U	-	2E+5	6E-5	2E-7	-	-
92 Uranium-240	D, see ²³⁰ U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see ²³⁰ U	-	3E+3	1E-6	4E-9	-	-
	Y, see ²³⁰ U	-	2E+3	1E-6	3E-9	-	-
92 Uranium-natural ³	D, see ²³⁰ U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
	W, see ²³⁰ U	-	8E-1	3E-10	9E-13	-	-
	Y, see ²³⁰ U	-	5E-2	2E-11	9E-14	-	-
93 Neptunium-232 ²	W, all compounds	1E+5	2E+3 Bone surf (5E+2)	7E-7 -	- 6E-9	2E-3 -	2E-2 -
93 Neptunium-233 ²	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93 Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93 Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7 -	- 2E-9	- 3E-4	- 3E-3
93 Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12 -	- 8E-14	- 9E-8	- 9E-7
93 Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 -	- 1E-10	- 5E-5	- 5E-4
93 Neptunium-237	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
93 Neptunium-238	W, all compounds	1E+3	6E+1 Bone surf (2E+2)	3E-8 -	- 2E-10	2E-5 -	2E-4 -

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
93	Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	9E-7 -	3E-9 -	- 2E-5	- 2E-4
93	Neptunium-240 ²	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235 ²	W, see ²³⁴ Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ²³⁴ Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see ²³⁴ Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 6E-8	- 6E-7
		Y, see ²³⁴ Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see ²³⁴ Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ²³⁴ Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see ²³⁴ Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see ²³⁴ Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-240	W, see ²³⁴ Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ²³⁴ Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-241	W, see ²³⁴ Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 -	- 8E-13	- 1E-6	- 1E-5
		Y, see ²³⁴ Pu	-	8E-1 Bone surf (1E+0)	3E-10 -	- 1E-12	- -	- -

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)	
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)			
94 Plutonium-242	W, see ²³⁴ Pu	8E-1	7E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ²³⁴ Pu	-	2E-2 Bone surf	7E-12	-	-	-
		-	(2E-2)	-	2E-14	-	-
94 Plutonium-243	W, see ²³⁴ Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
	Y, see ²³⁴ Pu	-	4E+4	2E-5	5E-8	-	-
94 Plutonium-244	W, see ²³⁴ Pu	8E-1	7E-3	3E-12	-	-	-
		Bone surf (2E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
	Y, see ²³⁴ Pu	-	2E-2 Bone surf	7E-12	-	-	-
		-	(2E-2)	-	2E-14	-	-
94 Plutonium-245	W, see ²³⁴ Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
	Y, see ²³⁴ Pu	-	4E+3	2E-6	6E-9	-	-
94 Plutonium-246	W, see ²³⁴ Pu	4E+2 LLI wall	3E+2	1E-7	4E-10	-	-
		(4E+2)	-	-	-	6E-6	6E-5
	Y, see ²³⁴ Pu	-	3E+2	1E-7	4E-10	-	-
95 Americium-237 ²	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95 Americium-238 ²	W, all compounds	4E+4	3E+3 Bone surf	1E-6	-	5E-4	5E-3
		-	(6E+3)	-	9E-9	-	-
95 Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95 Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95 Americium-241	W, all compounds	8E-1	6E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95 Americium-242m	W, all compounds	8E-1	6E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95 Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
		-	Bone surf (9E+1)	-	1E-10	-	-
95 Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
		Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
95	Americium-244m ²	W, all compounds	6E+4 St wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 -	- 1E-8 1E-3	- 1E-2	
95	Americium-244	W, all compounds	3E+3	2E+2 Bone surf (3E+2)	8E-8 -	- 4E-5 4E-10	4E-4 -	
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m ²	W, all compounds	5E+4 St wall (6E+4)	2E+5 -	8E-5 -	3E-7 -	- 8E-4	- 8E-3
95	Americium-246 ²	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1 Bone surf (8E+1)	6E-1 Bone surf (6E-1)	2E-10 -	- 9E-13	- 1E-6	- 1E-5
96	Curium-241	W, all compounds	1E+3	3E+1 Bone surf (4E+1)	1E-8 -	- 5E-11	2E-5 -	2E-4 -
96	Curium-242	W, all compounds	3E+1 Bone surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 -	- 4E-13	- 7E-7	- 7E-6
96	Curium-243	W, all compounds	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 -	- 2E-14	- 3E-8	- 3E-7
96	Curium-244	W, all compounds	1E+0 Bone surf (3E+0)	1E-2 Bone surf (2E-2)	5E-12 -	- 3E-14	- 3E-8	- 3E-7
96	Curium-245	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-246	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-247	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96	Curium-248	W, all compounds	2E-1 Bone surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 -	- 4E-15	- 5E-9	- 5E-8

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion	INHALATION		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	ALI (μCi)				DAC (μCi/ml)
96	Curium-249 ²	W, all compounds	5E+4	2E+4 Bone surf	7E-6	-	7E-4	7E-3
			-	(3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2 Bone surf	3E-4 Bone surf	1E-13	-	-	-
			(6E-2)	(5E-4)	-	8E-16	9E-10	9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2 Bone surf	2E+0 Bone surf	7E-10	-	-	-
			(5E+2)	(4E+0)	-	5E-12	6E-6	6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2 Bone surf	1E-7	-	1E-4	1E-3
			-	(7E+2)	-	1E-9	-	-
98	Californium-244 ²	W, all compounds except those given for Y	3E+4 St wall	6E+2	2E-7	8E-10	-	-
			(3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98	Californium-246	W, see ²⁴⁴ Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ²⁴⁴ Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see ²⁴⁴ Cf	8E+0 Bone surf	6E-2 Bone surf	3E-11	-	-	-
			(2E+1)	(1E-1)	-	2E-13	2E-7	2E-6
		Y, see ²⁴⁴ Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see ²⁴⁴ Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	-	-	-
			(1E+0)	(9E-3)	-	1E-14	2E-8	2E-7
		Y, see ²⁴⁴ Cf	-	1E-2 Bone surf	4E-12	-	-	-
			-	(1E-2)	-	2E-14	-	-
98	Californium-250	W, see ²⁴⁴ Cf	1E+0 Bone surf	9E-3 Bone surf	4E-12	-	-	-
			(2E+0)	(2E-2)	-	3E-14	3E-8	3E-7
		Y, see ²⁴⁴ Cf	-	3E-2	1E-11	4E-14	-	-

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)		
98	Californium-251	W, see ²⁴⁴ Cf	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12	-	-	2E-7
		Y, see ²⁴⁴ Cf	-	1E-2 Bone surf (1E-2)	4E-12	-	-	-
98	Californium-252	W, see ²⁴⁴ Cf	2E+0 Bone surf (5E+0)	2E-2 Bone surf (4E-2)	8E-12	-	-	-
		Y, see ²⁴⁴ Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see ²⁴⁴ Cf	2E+2 Bone surf (4E+2)	2E+0	8E-10	3E-12	-	-
		Y, see ²⁴⁴ Cf	-	2E+0	7E-10	2E-12	5E-6	5E-5
98	Californium-254	W, see ²⁴⁴ Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see ²⁴⁴ Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4 Bone surf (1E+3)	5E+2	2E-7	-	6E-4	6E-3
99	Einsteinium-251	W, all compounds	7E+3	9E+2 Bone surf (1E+3)	4E-7	-	1E-4	1E-3
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
99	Einsteinium-254	W, all compounds	(3E+2) Bone surf (2E+1)	-	-	-	4E-6	4E-5
			8E+0 Bone surf (2E+1)	7E-2 Bone surf (1E-1)	3E-11	-	-	-
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1 Bone surf (4E+1)	2E-1 Bone surf (2E-1)	7E-11	-	-	-
101	Mendelevium-257	W, all compounds	7E+3	8E+1 Bone surf	4E-8	-	1E-4	1E-3

Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)	
101	Mendelevium-258	W, all compounds	(9E+1)	-	1E-10	-	-
			3E+1	2E-1	1E-10	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7
							6E-6
		- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours Submersion ¹	-	2E+2	1E-7	1E-9	-
		- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours	-	2E-1	1E-10	1E-12	1E-8
		- Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radio-nuclide in the mixture is not known	-	4E-4	2E-13	1E-15	2E-9
							2E-8

FOOTNOTES:

¹“Submersion” means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

²These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class “Submersion,” are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (see 40.17)

³For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see 40.15(5)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

$$SA = 3.6E-7 \text{ curies/gram U U-depleted}$$

$$SA = [0.4 + 0.38 (\text{enrichment}) + 0.0034 (\text{enrichment})^2] E-6, \text{ enrichment} \geq 0.72$$

where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

If it is known that Ac-227-D and Cm-250-W are not present

-	7E-4	3E-13	-	-	-
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If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present

-	7E-3	3E-12	-	-	-
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If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present

-	7E-2	3E-11	-	-	-
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Atomic Radio-nuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	INHALATION ALI (μCi) DAC (μCi/ml)		Air (μCi/ml)	Water (μCi/ml)	
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present							
		-	7E-1	3E-10	-	-	-
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D,Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D, W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present							
		-	7E+0	3E-9	-	-	-
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W, Y, Cm-248-W, and Cm-250-W are not present							
		-	-	-	-	1E-14	-
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present							
		-	-	-	1E-13	-	-
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D, W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present							
		-	-	-	-	1E-12	-
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present							
		-	-	-	-	1E-6	1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B, Chapter 40 for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

EXAMPLE: If radionuclides "A," "B," and "C" are present in concentrations C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

[ARC 8982B, IAB 8/11/10, effective 9/15/10]

CHAPTER 40

APPENDIX C

QUANTITIES¹ OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity (μ Ci)*	Radionuclide	Quantity (μ Ci)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	100	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100

Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000

Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		
Niobium-88	1,000	Palladium-101	1,000
Niobium-89m		Palladium-103	100
(66 min)	1,000	Palladium-107	10
Niobium-89		Palladium-109	100
(122 min)	1,000	Silver-102	1,000
Niobium-90	100	Silver-103	1,000
Niobium-93m	10	Silver-104m	1,000
Niobium-94	1	Silver-104	1,000
Niobium-95m	100	Silver-105	100
Niobium-95	100	Silver-106m	100
Niobium-96	100	Silver-106	1,000
Niobium-97	1,000	Silver-108m	1
Niobium-98	1,000	Silver-110m	10
Molybdenum-90	100	Silver-111	100
Molybdenum-93m	100	Silver-112	100
Molybdenum-93	10	Silver-115	1,000
Molybdenum-99	100	Cadmium-104	1,000
Molybdenum-101	1,000	Cadmium-107	1,000
Technetium-93m	1,000	Cadmium-109	1
Technetium-93	1,000	Cadmium-113m	0.1
Technetium-94m	1,000	Cadmium-113	100
Technetium-94	1,000	Cadmium-115m	10
Technetium-96m	1,000	Cadmium-115	100
Technetium-96	100	Cadmium-117m	1,000
Technetium-97m	100	Cadmium-117	1,000
Technetium-97	1,000	Indium-109	1,000
Technetium-98	10	Indium-110m	
Technetium-99m	1,000	(69.1m)	1,000
Technetium-99	100	Indium-110	
Technetium-101	1,000	(4.9h)	1,000
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000

Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120		Iodine-131	1
(16m)	1,000	Iodine-132m	100
Antimony-120		Iodine-132	100
(5.76d)	100	Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128		Xenon-127	1,000
(10.4m)	1,000	Xenon-129m	1,000
Antimony-128		Xenon-131m	1,000
(9.01h)	100	Xenon-133m	1,000
Antimony-129	100	Xenon-133	1,000
Antimony-130	1,000	Xenon-135m	1,000

Antimony-131	1,000	Xenon-135	1,000
Tellurium-116	1,000	Xenon-138	1,000
Tellurium-121m	10	Cesium-125	1,000
Tellurium-121	100	Cesium-127	1,000
Tellurium-123m	10	Cesium-129	1,000
Tellurium-123	100	Cesium-130	1,000
Tellurium-125m	10	Cesium-131	1,000
Tellurium-127m	10	Cesium-132	100
Tellurium-127	1,000	Cesium-134m	1,000
Tellurium-129m	10	Cesium-134	10
Tellurium-129	1,000	Cesium-135m	1,000
Tellurium-131m	10	Cesium-135	100
Tellurium-131	100	Cesium-136	10
Tellurium-132	10	Cesium-137	10
Tellurium-133m	100	Cesium-138	1,000
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100

Cerium-143	100	Europium-150	
Cerium-144	1	(12.62h)	100
Praseodymium-136	1,000	Europium-150	
Praseodymium-137	1,000	(34.2y)	1
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m		Lutetium-169	100
(5.0h)	1,000	Lutetium-170	100
Terbium-156m		Lutetium-171	100
(24.4h)	1,000	Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10
Terbium-158	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100

Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	
Tungsten-176	1,000	(1.4m)	10
Tungsten-177	1,000	Iridium-192	
Tungsten-178	1,000	(73.8d)	1
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182		Platinum-193m	100
(12.7h)	1,000	Platinum-193	1,000

Rhenium-182 (64.0h)	100	Platinum-195m	100
Rhenium-184m	10	Platinum-197m	1,000
Rhenium-184	100	Platinum-197	100
Rhenium-186m	10	Platinum-199	1,000
Rhenium-186	100	Platinum-200	100
Rhenium-187	1,000	Gold-193	1,000
Rhenium-188m	1,000	Gold-194	100
Rhenium-188	100	Gold-195	10
Rhenium-189	100	Gold-198m	100
Osmium-180	1,000	Gold-198	100
Osmium-181	1,000	Gold-199	100
Osmium-182	100	Gold-200m	100
Osmium-185	100	Gold-200	1,000
Osmium-189m	1,000	Gold-201	1,000
Osmium-191m	1,000	Mercury-193m	100
Osmium-191	100	Mercury-193	1,000
Osmium-193	100	Mercury-194	1
Osmium-194	1	Mercury-195m	100
Iridium-182	1,000	Mercury-195	1,000
Iridium-184	1,000	Mercury-197m	100
Iridium-185	1,000	Mercury-197	1,000
Iridium-186	100	Mercury-199m	1,000
Iridium-187	1,000	Mercury-203	100
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-200	1,000	Actinium-224	1
Thallium-201	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100

Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-211	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236	
Francium-222	100	(1.15E+5)	0.001
Neptunium-236		Curium-242	0.01
(22.5h)	1	Curium-243	0.001
Neptunium-237	0.001	Curium-244	0.001
Neptunium-238	10	Curium-245	0.001
Neptunium-239	100	Curium-246	0.001
Neptunium-240	1,000	Curium-247	0.001
Plutonium-234	10	Curium-248	0.001
Plutonium-235	1,000	Curium-249	1,000
Plutonium-236	0.001	Berkelium-245	100
Plutonium-237	100	Berkelium-246	100
Plutonium-238	0.001	Berkelium-247	0.001
Plutonium-239	0.001	Berkelium-249	0.1
Plutonium-240	0.001	Berkelium-250	10
Plutonium-241	0.01	Californium-244	100

Plutonium-242	0.001	Californium-246	1
Plutonium-243	1,000	Californium-248	0.01
Plutonium-244	0.001	Californium-249	0.001
Plutonium-245	100	Californium-250	0.001
Americium-237	1,000	Californium-251	0.001
Americium-238	100	Californium-252	0.001
Americium-239	1,000	Californium-253	0.1
Americium-240	100	Californium-254	0.001
Americium-241	0.001	Einsteinium-250	100
Americium-242m	0.001	Einsteinium-251	100
Americium-242	10	Einsteinium-253	0.1
Americium-243	0.001	Einsteinium-254m	1
Americium-244m	100	Einsteinium-254	0.01
Americium-244	10	Fermium-252	1
Americium-245	1,000	Fermium-253	1
Americium-246m	1,000	Fermium-254	10
Americium-246	1,000	Fermium-255	1
Curium-238	100	Fermium-257	0.01
Curium-240	0.1	Mendelevium-257	10
Curium-241	1	Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

*To convert μCi to kBq , multiply the μCi value by 37.

¹The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to this chapter, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 μCi). Values of 3.7 MBq (100 μCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 μCi), to take into account their low specific activity.

NOTE: For purposes of 40.61(5), 40.64(1), and 40.95(1) where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1"—that is, unity.

CHAPTER 40

APPENDIX D

REQUIREMENTS FOR TRANSFERS AND MANIFESTS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES

As used in this appendix, the following definitions apply:

“Chelating agent” means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carboric acid, and glucinic acid).

“Chemical description” means a description of the principal chemical characteristics of a low-level radioactive waste.

“Computer-readable medium” means that the regulatory agency’s computer can transfer the information from the medium into its memory.

“Consignee” means the designated receiver of the shipment of low-level radioactive waste.

“Decontamination facility” means a facility operating under an agreement state or Nuclear Regulatory Commission license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives and, for purposes of this appendix, is not considered to be a consignee for LLW shipments.

“Disposal container” means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see “high integrity container”). Note that for some shipments, the disposal container may be the transport package.

“EPA identification number” means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

“Forms 540, 540A, 541, 541A, 542, and 542A” are official forms referenced in this appendix. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Forms 541 (and 541A) and Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

“Generator” means a licensee operating under an agreement state or Nuclear Regulatory Commission license who (1) is a waste generator as defined in this rule, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

“High integrity container (HIC)” means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet United States Department of Transportation requirements for a Type A package.

“Land disposal facility” means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this appendix, a “geologic repository” as defined in 10 CFR Part 60 is not considered a land disposal facility.

“Package” means the assembly of components necessary to ensure compliance with the packaging requirements of United States Department of Transportation regulations, together with its radioactive contents, as presented for transport.

“Physical description” means the items called for on Form 541 to describe a low-level radioactive waste.

“Residual waste” means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

“Shipper” means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

“Shipping paper” means Form 540 and, if required, Form 540A which includes the information required by United States Department of Transportation in 49 CFR Part 172.

“Uniform Low-Level Radioactive Waste Manifest” or “uniform manifest” means the combination of Forms 540, 541 and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

“Waste collector” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

“Waste description” means the physical, chemical and radiological description of a low-level radioactive waste as called for on Form 541.

“Waste generator” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a “waste generator” if the transfer of low-level radioactive waste from its facility is defined as “residual waste.”

“Waste processor” means an entity, operating under an agreement state or Nuclear Regulatory Commission license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

“Waste type” means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by this agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the “waste generator” or “generator,” as defined in this part; or

(c) Radioactively contaminated material to a “waste processor” that becomes the processor’s “residual waste.”

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0111, telephone (301)415-5877 or by visiting the NRC’s website at www.nrc.gov and selecting forms from the index found on the home page.

This appendix includes information requirements of the United States Department of Transportation, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste required to meet Environmental Protection Agency regulations, as codified in 40 CFR Parts 259, 261, or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

Information Requirements

A. General Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility's address, and telephone number of the licensee shipping the waste;
2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
3. The name, address, and telephone number, or the name and EPA identification number, for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;
2. The total number of packages/disposal containers;
3. The total disposal volume and disposal weight in the shipment;
4. The total radionuclide activity in the shipment;
5. The activity of each of the radionuclides, H-3, C-14, Tc-99, and I-129 contained in the shipment; and
6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;
3. The volume displaced by the disposal container;
4. The gross weight of the disposal container, including the waste;
5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
6. A physical and chemical description of the waste;
7. The total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;
8. The approximate volume of waste within a container;
9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;
10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;
11. The total radioactivity within each container; and
12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;
2. A physical and chemical description of the waste;
3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multigenerator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this appendix.) It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the United States Department of Transportation and this agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1. through A.9. of this appendix. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4. through A.9. of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with 10 CFR 61.55;

3. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the

manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

6. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5. of this section;

7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41); and

9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

4. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3. of this section;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph E.1. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR 61.55 and 61.57;

5. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

7. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6. of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and this agency of any shipment, or part of a shipment, that has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the license is terminated; and

3. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with this agency. Each licensee who conducts a trace investigation shall file a written report with this agency within two weeks of completion of the investigation.

[ARC 3746C, IAB 4/11/18, effective 5/16/18]

CHAPTER 40

APPENDIX E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL
RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b) Classes of waste.

1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II. (a). If Class A waste also meets the stability requirements set forth in Section II. (b), it is not necessary to segregate the waste for disposal.

2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE I

Radionuclide	Concentration	
	curie/cubic meter ^a	nanocurie/gram ^b
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	

Tc-99	3
I-129	0.08
Alpha emitting transuranic radionuclides with half-life greater than five years	100
Pu-241	3,500
Cm-242	20,000
Ra-226	100

^a To convert the Ci/m³ values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37.

^bTo convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

- 1) If the concentration does not exceed the value in Column 1, the waste is Class A.
- 2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.
- 3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.
- 4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
- 5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE II

Radionuclide	Concentration, Column 1	curie/cubic meter *	
		Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*AGENCY NOTE: To convert the Ci/m³ value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m³ value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

- 1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

g) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

h) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m³ (50 Ci/m³) and Cs-137 in a concentration of 814 GBq/m³ (22 Ci/m³). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

II. Radioactive Waste Characteristics

a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this chapter, the site license conditions shall govern.

2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.⁴

8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 100 Ci (3.7 TBq) per container.

⁴See 641—38.2 of these rules for the definition of pyrophoric.

9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself,

processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

CHAPTER 40

APPENDIX F

QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100

<u>Material</u>	<u>Microcurie*</u>
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100

<u>Material</u>	<u>Microcurie*</u>
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10

<u>Material</u>	<u>Microcurie*</u>
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10

<u>Material</u>	<u>Microcurie*</u>
Tungsten-185	10
Tungsten-187	100
Uranium (natural)**	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha-emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

*To convert μCi to kBq , multiply the μCi value by 37.

**Based on alpha disintegration rate of U-238, U-234, and U-235.

NOTE: This Appendix is retained for use by those agreement states that need to adopt decommissioning regulations compatible with the U.S. Nuclear Regulatory Commission.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1"—that is, unity.

CHAPTER 40

APPENDIX G

Reserved

APPENDIX H

NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16.0
Americium-241/Be	60	1,600	0.6	16.0
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14.0
Cesium-137	100	2,700	1.0	27.0
Gadolinium-153	1,000	27,000	10.0	270.0
Iridium-192	80	2,200	0.8	22.0
Plutonium-238	60	1,600	0.6	16.0
Plutonium-239/Be	60	1,600	0.6	16.0
Polonium-210	60	1,600	0.6	16.0
Promethium-147	40,000	1,100,000	400.0	11,000.0
Radium-226	40	1,100	0.4	11.0
Selenium-75	200	5,400	2.0	54.0
Strontium-90	1,000	27,000	10.0	270.0
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200.0	5,400.0
Ytterbium-169	300	8,100	3.0	81.0

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 41
SAFETY REQUIREMENTS FOR THE USE OF
RADIATION MACHINES AND CERTAIN USES
OF RADIOACTIVE MATERIALS

641—41.1(136C) X-rays in the healing arts.

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of May 16, 2018.

41.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

“*Accessible surface*” means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

“*Added filtration*” means any filtration which is in addition to the inherent filtration.

“*Aluminum equivalent*” means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

“*Attenuation block*” means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

“*Automatic exposure control (AEC)*” means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also “Phototimer”). (Includes devices such as phototimers and ion chambers.)

“*Base density*” means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

“*Base plus fog density*” means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

“*Beam monitoring system*” means a system designed to detect and measure the radiation present in the useful beam.

“*C-arm X-ray system*” means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

“*Cassette*” means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

“*Cephalometric device*” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“*Certified components*” means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the “Radiation Control for Health and Safety Act of 1968,” the Food and Drug Administration.

“*Certified system*” means any X-ray system which has one or more certified component(s).

“*Coefficient of variation*” or “*C*” means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

\bar{s} = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

“*Computed tomography*” means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

“*Control chart*” means a chart used to record (and control) the results of quality control testing as a function of time.

“*Control limit*” means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

“*Control panel*” (see X-ray control panel).

“*Cooling curve*” means the graphical relationship between heat units stored and cooling time.

“*CT*” (see “*Computed tomography*”).

“*Dead-man switch*” means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

“*Dedicated mammography equipment*” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“*Densitometer*” means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

“*Detents*” means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

“*Developer*” means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

“*Developer replenishment*” means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

“*Diagnostic mammography*” means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

“*Diagnostic source assembly*” means the tube housing assembly with a beam-limiting device attached.

“*Direct scattered radiation*” means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see “*Scattered radiation*”).

“*Entrance exposure rate*” means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

“*Equipment*” (see “*X-ray equipment*”).

“*Field emission equipment*” means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“*Filter*” means material placed in the useful beam to preferentially absorb selected radiations.

“*Fixer*” means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

“*Fixer retention*” means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

“*Fluoroscopic imaging assembly*” means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical

interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

“Focal spot (actual)” means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

“Focal spot size” means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

“Fog” means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

“General purpose radiographic X-ray system” means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

“Gonad shield” means a protective barrier for the testes or ovaries.

“Healing arts screening” means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)“a”(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

“Heat unit” means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., $kVp \times mA \times \text{second}$.

“Image contrast” means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attenuation difference or light exposure difference.

“Image intensifier” means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

“Image noise” See “Radiographic noise.”

“Image quality” means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

“Image sharpness” means the overall impression of detail and clarity in a radiographic image.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Kilovolts peak” (see “Peak tube potential”).

“kVp” (see “Peak tube potential”).

“kWs” means kilowatt second.

“Leakage technique factors” means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

“*Linear attenuation coefficient*” or “ μ ” means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

“*Line-voltage regulation*” means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

V_n = No-load line potential and

V_l = Load line potential.

“*mAs*” means milliamperere second.

“*Maximum line current*” means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

“*Mobile X-ray equipment*” (see “X-ray equipment”).

“*PBL*” (see “Positive beam limitation”).

“*Phototimer*” means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see “Automatic exposure control”).

“*PID*” (see “Position indicating device”).

“*Portable X-ray equipment*” (see “X-ray equipment”).

“*Position indicating device*” means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

“*Positive beam limitation*” means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

“*Processor*” means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

“*Protective apron*” means an apron made of radiation-absorbing materials used to reduce radiation exposure.

“*Protective glove*” means a glove made of radiation-absorbing materials used to reduce radiation exposure.

“*Quality assurance*” means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

“*Quality control*” means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

“*Radiation therapy simulation system*” means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

“*Radiograph*” means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

“*Radiographic contrast*” means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

“*Radiographic noise*” means unwanted fluctuations in optical density on the screen-film image.

“*Rating*” means the operating limits as specified by the component manufacturer.

“*Recording*” means producing a permanent form of an image resulting from X-ray photons.

“*Repeat (or reject) analysis*” means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

“*Replenishment rate*” means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

“Response time” means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

“Safelight” means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

“Screen” means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

“Screen-film combination” means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

“Screen-film contact” means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

“Sensitometer” means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

“Sensitometric strip” means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

“Sensitometry” means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

“SID” (see “Source-image receptor distance”).

“Source” means the focal spot of the X-ray tube.

“Source-image receptor distance” means the distance from the source to the center of the input surface of the image receptor.

“Spot check” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“Spot film” means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

“Spot-film device” means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

“Stationary X-ray equipment” (see “X-ray equipment”).

“Technique factors” means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“Tomogram” means the depiction of the X-ray attenuation properties of a section through the body.

“Tube rating chart” means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

“Useful beam” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

“Variable-aperture beam-limiting device” means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

“Viewbox” means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

“Visible area” means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

“X-ray control panel” means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

“X-ray equipment” means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. *“Mobile X-ray equipment”* means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. *“Portable X-ray equipment”* means X-ray equipment designed to be hand-carried but used with a tripod or other stabilization mechanism so the operator is not holding the equipment during exposure.

c. *“Stationary X-ray equipment”* means X-ray equipment which is installed in a fixed location.

d. *“Handheld X-ray equipment”* means X-ray equipment designed by the manufacturer to be handheld by the operator during the exposure. X-ray equipment designed without a backscatter shield is prohibited.

“X-ray exposure control” means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

“X-ray field” means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

“X-ray high-voltage generator” means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

“X-ray system” means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

“X-ray table” means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) Administrative controls.

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant’s administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum tests performed by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (41.1(5) “c”), and minimum SSD (41.1(5) “f”) annually.

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant’s agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42, as applicable, and shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

2. Type and size of the film or film-screen combination to be used;

3. Type and focal distance of the grid to be used, if any;

4. Source to image receptor distance to be used, except for dental intraoral radiography; and

5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3) "a"(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)“a”(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)“a”(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)“a”(5)“2”;

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intraoral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations, excluding intraoral dental imaging, where it is impractical to transfer the patient(s) to a stationary X-ray installation. Handheld mobile X-ray equipment may be used for routine intraoral dental imaging in place of stationary equipment. Handheld X-ray equipment shall be used only for intraoral dental radiography.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(4) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

b. Information and maintenance record and associated information. Records in 41.1(3)“b”(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)“b”(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

- (1) User’s manual for the X-ray system;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3)“f” shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom

for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3) "f" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 $\mu\text{C}/\text{kg}$) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 $\mu\text{C}/\text{kg}$) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Reserved.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)“e” shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)“e”(1)“1” is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)“h”(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator’s position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer’s standards.

41.1(5) Fluoroscopic X-ray systems except for computed tomography X-ray systems. All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)“a”(2)“1” apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;

- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices

manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5) "a"(2) and 41.1(5) "a"(3), that means:

1. Shall be designed for use only in the event of system failure;
2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls

shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)“c” shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;

- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or

- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)“c”(1)“3”;

- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)“c”(1)“3.”

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μ C/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-skin distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,

(2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,

(3) 30 centimeters on all mobile fluoroscopes, and

(4) 20 centimeters for mobile fluoroscopes used for specific surgical application.

(5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)“a”(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)“a”(5).

(3) The agency may grant exemptions to 41.1(5)“h”(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)“d” when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)“a,” “c,” “d,” and “g” provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)“g” are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac

procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(3) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes. The use of fluoroscopy by radiologist assistants shall be as defined in 641—42.6(136C).

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6) "h"(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.
 - Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.
 - The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.
3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)“a”(1)“1” and “2” provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)“a”(1)“1” and “2”; and the purpose of 41.1(6)“a”(1)“1” and “2” will be met by other methods.
 - (2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)“a”(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:
 1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;
 2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
 3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
 - (3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
 - (4) Reserved.
 - (5) X-ray systems other than those described in 41.1(6)“a”(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.
 1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.
 2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.
 3. 41.1(6)“a”(5)“1” and “2” may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)“a”(1) or, when alignment means are also provided, may be met with either:
 - An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
 - A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.
- b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6) "b"(2) "2"; or

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure. Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6) "b"(3) "2" shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6) "b"(3) "4," and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{\max}) minus the minimum exposure period (T_{\min}) when four timer tests are performed:

$$\bar{T} \geq 5 (T_{\max} - T_{\min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C \text{ kg}^{-1}\text{s}^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average $C \text{ kg}^{-1}\text{s}^{-1}$ (mR/s) values.

c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens ($0.516 \mu\text{C}/\text{kg}$) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliamperere-seconds product ($C \text{ kg}^{-1}\text{mAs}^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of mR/mAs (or $C \text{ kg}^{-1}\text{mAs}^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X-ray systems.

1. There shall be provided a means of stepless adjustment of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when

- Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6) "h" (3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

- The sum of the length and width differences as stated in 41.1(6) "h" (2) "1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6) "h" (2) "1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6) "h" (2) "1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6) "a" or 41.1(6) "h" (2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

j. Systems used in a clinical (nonsurgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3) "d."

41.1(7) Intraoral dental radiographic systems. In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used. Additional requirements specific to handheld dental X-ray equipment are outlined in 41.1(7) "i."

a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)“c.”

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator’s protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to “zero.”

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half ($\frac{1}{2}$) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of $C\ kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the equipment while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)“a”(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)“c”(5)“1.”

- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 6 feet (1.8 meters) from the tube housing assembly while making exposure.

3. Portable dental X-ray systems designed with a backscatter shield may be used without an additional protective barrier, but the operator must stand directly behind the equipment to allow the shield to function as designed.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliamperere-seconds product, in units of $C\text{ kg}^{-1}\text{ mAs}^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. kVp limitations. Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID for stationary or mobile systems shall not be held by the operator during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7) "b"(1).

(4) Dental fluoroscopy without image intensification shall not be used.

i. Handheld dental X-ray systems. Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated pursuant to this subrule.

(1) Operators shall be specifically trained to operate the equipment. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

(2) Protective aprons of not less than 0.25 millimeter lead equivalent shall be provided for operators to wear while operating the equipment.

(3) Dosimetry shall be provided for operators who are expected to exceed 10 percent of the annual occupational dose limit as outlined in 641—40.84(136C).

(4) Operators shall operate the equipment according to the manufacturer's instructions.

(5) The image receptor used must be digital radiography (DR), computed radiography (CR), or intraoral film with a speed class designated as “E/F” or a film with a faster speed designation than “F” or “E/F.”

(6) No individual except the equipment operator may be within a radius of at least 6 feet from the patient during exposures.

(7) The equipment shall not be operated unless the backscatter shield is in place as designed by the manufacturer.

(8) The equipment shall not be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

(9) The equipment shall be held without any motion during a patient examination. If the operator has difficulty in holding the equipment stationary, the operator shall use a tube stand. The equipment shall be operated on a tube stand whenever practicable to avoid unnecessary motion and retakes.

(10) When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

41.1(8) Reserved.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

c. Reserved.

d. Specific operating procedures must be prepared and made available at the operator’s position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer’s specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) *Veterinary medicine radiographic installations.*

a. *Equipment.*

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4)“c.”

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. *Operator protection.*

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 641—40.21(136C) and 641—subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1(136C) except for subrules 41.1(3) and 41.1(10).

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) Computed tomography X-ray systems.

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"*Computed tomography dose index*" means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around $z = 0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is nT .

"*Contrast scale*" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{\text{CS}} = \frac{\mu_x - \mu_w}{\overline{\text{CTN}}_x - \overline{\text{CTN}}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$\overline{\text{CTN}}_x$ = of the material of interest.

$\overline{\text{CTN}}_w$ = of water.

"*CS*" (see "*Contrast scale*").

"*CT conditions of operation*" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"*CTDI*" (see "*Computed tomography dose index*").

"*CT gantry*" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"*CTN*" (see "*CT number*").

“*CT number*” means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

“*Dose profile*” means the dose as a function of position along a line.

“*Elemental area*” means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also “*Picture element*”).

“*Multiple tomogram system*” means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

“*Noise*” means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{\text{CS}} \cdot s}{\mu_w}$$

where:

$\overline{\text{CS}}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

“*Nominal tomographic section thickness*” means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

“*Picture element*” means an elemental area of a tomogram.

“*Reference plane*” means a plane which is displaced from and parallel to the tomographic plane.

“*Scan*” means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

“*Scan increment*” means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

“*Scan sequence*” means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

“*Scan time*” means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

“*Single tomogram system*” means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

“*Tomographic plane*” means that geometric plane which is identified as corresponding to the output tomogram.

“*Tomographic section*” means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 41.1(11)“b”(1)“1.”

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11)“b”(2)“1” or “2,” the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter status indicators and control switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)“c.”

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI^{3/4} along the two axes specified in 41.1(11)“d”(2)“4” shall be measured. (For the purpose of determining the CTDI, the manufacturer’s statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)“d”(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)“d”(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)“d”(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 42.

[ARC 8659B, IAB 4/7/10, effective 5/12/10; ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3103C, IAB 6/7/17, effective 7/12/17; ARC 3746C, IAB 4/11/18, effective 5/16/18]

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) Purpose and scope.

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

41.2(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

“*Area of use*” means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

“*Associate radiation safety officer*” means an individual who:

a. Meets the requirements of 41.2(65) and 41.2(77); and

b. Is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the duties and tasks by the radiation safety officer on:

1. A specific medical use license issued by the NRC or an agreement state; or

2. A medical use permit issued by an NRC master material licensee.

“*Authorized medical physicist*” means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by this agency, the NRC, or an agreement state;

2. A medical use permit issued by an NRC master material licensee;

3. A permit issued by an NRC or agreement state broad scope medical use licensee; or

4. A permit issued by an NRC master material license broad scope medical use permittee.

“*Authorized nuclear pharmacist*” means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or:

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;

2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29) “j”(2)“3.” “*Authorized user*” means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67) “a,” 41.2(68) “a,” 41.2(69) “a,” 41.2(70) “a,” 41.2(72) “a,” 41.2(73) “a,” 41.2(81) “a,” or 41.2(82) “a,” or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or

4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

“*Dedicated check source*” means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

“*Management*” means the chief executive officer or that individual’s designee.

“*Medical institution*” means an organization in which several medical disciplines are practiced.

“*Mobile nuclear medicine service*” means the transportation and medical use of radioactive material.

“*Ophthalmic physicist*” means an individual who:

- a. Meets the requirements of 41.2(85) “a”(2) and 41.2(77); and

- b. Is identified as an ophthalmic physicist on a:

1. Specific medical use license issued by an NRC or an agreement state;

2. Permit issued by an NRC or agreement state broad scope medical use licensee;

3. Medical use permit issued by an NRC master material licensee; or

4. Permit issued by an NRC master material licensee broad scope medical use permittee.

“*Output*” means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

“*Pharmacist*” means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

“*Radiation safety officer*” means an individual who, in addition to the definition in 641—38.2(136C):

- a. Meets the requirements of 41.2(65) and 41.2(77); and

- b. Is identified as a radiation safety officer on:

1. A specific medical use license issued by the NRC or an agreement state; or

2. A medical use permit issued by an NRC master material licensee.

“*Stereotactic radiosurgery*” means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

“*Teletherapy*” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“*Unit dosage*” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“*Visiting authorized user*” means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) License required.

- a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28) “b” may apply for a Type A specific license of broad scope.

41.2(4) License amendments.

a. A licensee shall apply for and receive a license amendment:

- (1) Before using byproduct material for a method or type of medical use not permitted by the license issued under this rule;
- (2) Before permitting anyone to work as an authorized user or authorized nuclear pharmacist under the license unless the individual meets “visiting” status in accordance with 41.2(12);
- (3) Before changing a radiation safety officer;
- (4) Before permitting anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;
- (5) Before receiving byproduct material in excess of the amount authorized on the license;
- (6) Before adding to or changing the address or addresses of use identified in the application or on the license; and
- (7) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

b. License amendment exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

- (1) The provision of 41.2(4) “a”(2);
- (2) The provisions of 41.2(4) “a”(6) regarding additions to or changes in the areas of use only at the addresses specified in the license.

41.2(5) Notifications.

a. A licensee shall notify the agency no later than 30 days after:

- (1) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, or an ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;
- (2) The licensee permits an individual qualified to be a radiation safety officer under 41.2(65) and 41.2(77) to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with 41.2(10) “c”;
- (3) The licensee’s mailing address changes;
- (4) The licensee’s name changes but the name change does not constitute a transfer of control of the license as described in 641—paragraph 39.4(32) “b”; or
- (5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used.

b. Notifications requiring agency approval prior to implementation for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units include:

(1) Revisions to procedures required by 41.2(52), 41.2(59)“a,” 41.2(59)“b,” and 41.2(59)“c” as applicable, where such revision reduces radiation safety;

(2) Changes that could impact radiation levels in adjacent spaces, such as shielding or location of device.

c. The licensee shall mail the documents required in this subrule to the agency in accordance with 641—38.7(136C).

d. Notification exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provisions of 41.2(5)“a”(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist.

(2) The provisions of 41.2(5)“a”(5).

41.2(6) Maintenance of records.

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)“a” and “b.”

41.2(7) ALARA program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7)“a”:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)“b”(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) Radiation safety officer.

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;
2. Receiving and opening packages of radioactive material;
3. Storing radioactive material;
4. Keeping an inventory record of radioactive material;
5. Using radioactive material safely;
6. Taking emergency action if control of radioactive material is lost;
7. Performing periodic radiation surveys;
8. Performing checks and calibrations of survey instruments and other safety equipment;
9. Disposing of radioactive material;
10. Training personnel who work in or frequent areas where radioactive material is used or stored;

and

11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) Radiation safety committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) Reserved.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;
2. Members present;
3. Members absent;
4. Summary of deliberations and discussions;
5. Recommended actions and the numerical results of all ballots; and
6. Document any reviews required in 41.2(7) "c" and 41.2(9) "b."

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

- (1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
- (2) Review:
 1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;
 2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.
- (3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
- (4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;
- (5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;
- (6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;
- (7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and
- (8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) Authority and responsibilities for the radiation protection program.

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

- (1) Requests for a license application, renewal, or amendment before submittal to this agency;
- (2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and
- (3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on the license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c. For up to 60 days each year, a licensee may permit an individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10) "g," if the licensee takes the actions required in 41.2(10) "b," "e," "g," and "h" and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10) "c" if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of byproduct material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

- (1) Identify radiation safety problems;
- (2) Initiate, recommend, or provide corrective solutions;
- (3) Verify implementation of corrective actions; and
- (4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) Supervision.

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be made available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of byproduct material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3) "c," shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of the NRC or agreement state license that identifies the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist by name for the medical use being utilized by the licensee; and

(3) Only those procedures for which the visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist is specifically authorized by an NRC or agreement state license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user, visiting authorized medical physicist, visiting ophthalmic physicist, or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12) "a."

c. A licensee shall retain copies of the records specified in 41.2(12) "a" for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client's address;

(3) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of reportable medical events.*

a. When a reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the

reportable medical event. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the reportable medical event. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or
2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Reserved.

d. Each licensee shall retain a record of each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14) "a" to 41.2(14) "d" shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14) "f"(1) or (2).

1. The written report must include:

- The licensee's name;

- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14) "f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:
 - Name of the pregnant individual or the nursing child who is the subject of the event; and
 - Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

41.2(15) Suppliers. A licensee shall use for medical use only:

- a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and
- b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;
- c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) Quality control of imaging equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) Possession, use, calibration, and check of dose calibrators.

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

- (1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used

settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at 12-month intervals thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at 3-month intervals thereafter over the range of use between 30 microcuries (1.1 megabecquerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17) "b" following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years, except the geometry dependence test which shall be retained in accordance with 41.2(17) "b"(4). The records required by 41.2(17) "b" shall include:

(1) For 41.2(17) "b"(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17) "b"(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17) "b"(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17) "b"(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) Calibration and check of survey instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18) "a," the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18) "b," the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18) “*a*” for three years. The record shall include:

- (1) A description of the calibration procedure; and
- (2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18) “*a*,” “*b*,” and “*c*,” the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18) “*e*” shall be maintained by the licensee.

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains a photon-emitting radionuclide;

b. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “*j*” or equivalent NRC or agreement state requirements;

c. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

d. Retain a record of the assays required by 41.2(19) “*a*” for three years. To satisfy this requirement, the record shall contain the:

- (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
- (2) Patient’s or human research subject’s name and identification number if one has been assigned;
- (3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);
- (4) Date and time of the assay and administration; and
- (5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.*

a. Any person authorized by 41.2(3) for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the NRC, agreement state or licensing state and that do not exceed 30 millicuries (1.11 GBq) each;

(2) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

(3) Any byproduct material listed in 41.2(31) or 41.2(33) with a half-life greater than 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) or 1,000 times quantities in Appendix C of 641—Chapter 40 each; and

(4) Technetium-99m amounts as needed.

b. Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in 641—38.2(136C) except in accordance with the requirements in 41.2(41); or

(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this subrule.

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in 41.2(20) “*a*” or “*b*” need not list these sources on a specific medical use license.

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the

agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21) “*b*,” the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the “off” position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, the signature of the radiation safety officer and the signature of the individual performing the leak test.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at 6-month intervals. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, the signature of the radiation safety officer and the signature of the individual performing the physical inventory.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21) “*h*” for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) Syringe shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) Vial shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) Vial shield labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) Surveys for contamination and ambient radiation dose rate.

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26) "a" and "b" so as to be able to measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26) "a" and "b" and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26) "e" so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26) "e" and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26) "a," "b," and "e" for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

- (1) Guidance on the interruption or discontinuation of breast feeding, and
- (2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

- (1) Using the retained activity rather than the activity administered,
- (2) Using an occupancy factor less than 0.25 at 1 meter,
- (3) Using the biological or effective half-life, or
- (4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) Mobile nuclear medicine service technical requirements. A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17) "b"(1) "d" and "e" and 41.2(18) "d" and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28) "e" for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) Storage of volatiles and gases.

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) Decay-in-storage.

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

- (1) Holds radioactive material for decay a minimum of ten half-lives;
- (2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- (3) Removes or obliterates all radiation labels; and
- (4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30) "a," the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial

number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31) “b”(1) or the physician who is an authorized user in 41.2(31) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) Reserved.

41.2(33) *Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33) “b”(1) or the physician who is an authorized user in 41.2(33) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) *Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.*

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 41.2(34) “a.”

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 41.2(34)“a.”

d. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

e. A licensee shall report any measurement that exceeds the limits in 41.2(34)“a” at the time of generator elution, in accordance with the following:

(1) The licensee shall notify by telephone the agency and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 41.2(34)“a” at the time of generator elution. The telephone report to the agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

(2) By an appropriate method listed in 641—38.7(136C), the licensee shall submit a written report to the agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee’s equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee’s breakthrough determination; and the information in the telephone report as required by 41.2(34)“a.”

41.2(35) Control of aerosols and gases.

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)“a” at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)“d” shall be recorded and retained for the duration of the license.

41.2(36) Reserved.

41.2(37) *Use of unsealed byproduct material for which a written directive is required.* A licensee may use any unsealed byproduct material identified in 41.2(69) “b”(1)“2,” seventh bulleted paragraph, prepared for medical use and for which a written directive is required that:

a. Is obtained from:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29) “j” or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24) “h” or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69);

or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37) “b”(1) or the physician who is an authorized user in 41.2(37) “b”(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) *Safety instruction for radiopharmaceutical therapy and hospitalization.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(38) “a,” the instruction shall describe the licensee’s procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient’s or human research subject’s death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 641—40.116(136C) and adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(38) for three years. The records must include a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions for radiopharmaceutical therapy and hospitalization.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);

(2) Post the patient’s or human research subject’s door with a “Caution: Radioactive Material” sign and note on the door or on the patient’s or human research subject’s chart where and how long visitors may stay in the patient’s or human research subject’s room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list

of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) Reserved.

41.2(41) *Use of sealed sources for diagnosis.*

a. A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

b. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements in 41.2(15) "a" are met.

41.2(42) Reserved.

41.2(43) *Use of sources for manual brachytherapy.* A licensee shall use only brachytherapy sources:

a. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

b. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) *Safety instruction for manual brachytherapy.*

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving manual brachytherapy and cannot be released under 41.2(27). Refresher training shall be provided initially and at 12-month intervals or as required for patient care.

b. To satisfy 41.2(44) "a," the instruction shall describe:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
- (3) Procedures for patient or human research subject control;
- (4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);

(5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of safety instructions required by 41.2(44) for three years. The records must include a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction for three years.

41.2(45) Safety precautions for manual brachytherapy.

a. For each patient or human research subject receiving manual brachytherapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirem (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) Brachytherapy sources inventory.

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46) "b" and "c" for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) Release of patients or human research subjects treated with temporary implants.

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47) "a" for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) Reserved.

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.*

a. A licensee must only use sealed sources:

(1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(2) In research involving photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) "a" are met.

b. A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) "a" are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

a. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52) "a"(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52) "a"(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

d. A licensee shall:

(1) Ensure that vendor operational and safety training is provided to all individuals who will operate the unit prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(2) Provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual's assigned duties, in:

1. The procedures identified in 41.2(52) "a"(4); and

2. The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52), a description of the instruction, the date of instruction, the name of the attendee(s), and the name of the individual who gave the instruction.

g. A copy of the procedures required in 41.2(52) "d"(2) shall be retained until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

41.2(53) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned “on” following an interlock interruption until all treatment room entrance doors are closed and the beam “on-off” control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient’s or human research subject’s body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53) “a” through “e,” a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, “physically present” means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) Reserved.

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55) “d” for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a

dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55) "e."

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) Viewing system. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) Dosimetry equipment.

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57) "a." This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57) "a."

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57) "a" and "b," the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. *Teletherapy units.*

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58) "a"(1), full calibration measurements must include determination of:

1. The output within ± 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 4. Timer accuracy and linearity over the range of use;
 5. On-off error; and
 6. The accuracy of all distance measuring and localization devices in medical use.
- (3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58) "a"(2)"1" may be made using the dosimetry system that indicates relative dose rates.
- (4) A licensee shall make full calibration measurements required by 41.2(58) "a" in accordance with published protocols accepted by nationally recognized bodies.
- (5) A licensee shall mathematically correct the outputs determined in 41.2(58) "a"(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.
- (6) Full calibration measurements required by 41.2(58) "a"(1) and physical decay corrections required in 41.2(58) "a"(5) must be performed by the authorized medical physicist.
- (7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.
- b. Remote afterloader units.*
- (1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:
1. Before the first medical use of the unit; and
 2. Before medical use under the following conditions:
 - Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
 4. At intervals not exceeding one year for low-dose-rate remote afterloader units.
- (2) To satisfy the requirements of 41.2(58) "b"(1), full calibration measurements must include, as applicable, determination of:
1. The output within ± 5 percent;
 2. Source positioning accuracy to within ± 1 millimeter;
 3. Source retraction with backup battery upon power failure;
 4. Length of the source transfer tubes;
 5. Timer accuracy and linearity over the typical range of use;
 6. Length of the applicators; and
 7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- (3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.
- (4) A licensee shall make full calibration measurements required by 41.2(58) "b"(1) in accordance with published protocols accepted by nationally recognized bodies.
- (5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58) "b"(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58)“b.”

(7) A licensee shall mathematically correct the outputs determined in 41.2(58)“b”(2)“1” for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58)“b”(1) and physical decay corrections required by 41.2(58)“b”(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)“c”(1), full calibration measurements must include determination of:

1. The output within ± 3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitches;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)“c”(2)“1” may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)“c”(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)“c”(2)“1” at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)“c”(1) and physical decay corrections required in 41.2(58)“c”(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)“a”(7).

41.2(59) Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and

6. The difference between the measurement made in 41.2(59) "a"(1)"5" and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59) "a"(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59) "a"(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59) "a." The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59) "a"(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low-dose-rate remote afterloader unit; and
3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59)“b”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59)“b”(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit’s computer; and
8. Decayed source(s) activity in the unit’s computer.

(5) If the results of the spot checks required in 41.2(59)“b”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)“b”(4). The record must include:

1. The date of the spot check;
2. The manufacturer’s name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59)“b”(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59)“c”(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59)“c”(1)“1,” spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).

2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);
 - The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
 - Source output against computer calculation;
 - Timer accuracy and linearity over the range of use;
 - On-off error; and
 - Trunnion centricity.
- (4) To satisfy the requirements of 41.2(59) “c”(1) “2” and “3,” spot checks must ensure proper functioning of:
1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Timer termination;
 5. Radiation monitors used to indicate room exposures; and
 6. Emergency off buttons.
- (5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59) “c”(3) that is not operating properly.
- (6) If the results of the spot checks required in 41.2(59) “c”(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- (7) A licensee shall retain for three years a record of each spot check required by 41.2(59) “c”(3) and (4). The record must include:
1. The date of the spot check;
 2. The manufacturer’s name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
 3. An assessment of timer linearity and accuracy;
 4. The calculated on-off error;
 5. A determination of trunnion centricity;
 6. The difference between the anticipated output and the measured output;
 7. An assessment of source output against computer calculations;
 8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
 9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.
- (8) A licensee shall retain a copy of the procedures required in 41.2(59) “c”(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.
- 41.2(60) Radiation surveys for teletherapy facilities.**
- a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
 - b. The licensee shall make the survey required in 41.2(60) “a” at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.
 - c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason

the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59) "g" for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61) "a" indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62) "a," and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the NRC or an agreement state.

c. A licensee shall maintain a record of the full inspection and servicing for the duration of the use of the unit. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(65) "d." The names of the board certifications

that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
2. Have two years of either full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), 41.2(69), or 41.2(75); and
3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has:

(1) Completed a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity;
 - Radiation biology; and
 - Radiation dosimetry; and
2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an NRC or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of byproduct material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on an NRC or agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:
 - Shipping, receiving, and performing related radiation surveys;
 - Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - Securing and controlling byproduct material;
 - Using administrative controls to avoid mistakes in the administration of byproduct material;
 - Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - Using emergency procedures to control byproduct material; and
 - Disposing of byproduct material; and

(2) This individual must obtain a written attestation signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in 41.2(65) "b"(1) and 41.2(65) "d" and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

c. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(74)“a,” has experience in radiation safety aspects of similar types of use of byproduct material for which the licensee is seeking the approval of the individual as a radiation safety officer or an associate radiation safety officer, and meets the requirements in 41.2(65)“d”; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an NRC or agreement state license, a permit issued by an NRC master material licensee, a permit issued by an NRC or agreement state licensee of broad scope, or a permit issued by an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer and meets the requirements in 41.2(65)“d”; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC master material licensee. The individual must also meet the requirements in 41.2(65)“d”; and

d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

41.2(66) Reserved.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67)“c”(1)“1” and “2”; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69) or meets equivalent NRC or agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(67) “c”(1) and is able to independently fulfill the radiation safety-related duties as an authorized user under 41.2(31). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69), or 41.2(75) or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69), or 41.2(75), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(67) “c”(1).

41.2(68) Training for imaging and localization studies. Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed byproduct material for the uses authorized under 41.2(33) to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 41.2(68) “c”(1) “1” and “2”; and

- (2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

- b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68) “c”(1) “2,” seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

- c. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) “c”(1) “2,” seventh bulleted paragraph; 41.2(75); or equivalent NRC or agreement state requirements. An authorized nuclear pharmacist who meets the requirements in 41.2(75) or 41.2(78) may provide the supervised work experience for the seventh bulleted paragraph of 41.2(68) “c”(1) “2.” Work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

- Calculating, measuring, and safely preparing patient or human research subject dosages;

- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(68) "c"(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or 41.2(75), or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68) "c"(1)"2," seventh bulleted paragraph; or 41.2(75); or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(68) "c"(1).

41.2(69) Training for use of unsealed byproduct material for which a written directive is required. Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 41.2(37) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(69) "b"(1)"2," seventh bulleted paragraph. The names of the board certificates that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 41.2(69) "b"(1)"1" through 41.2(69) "b"(1)"2," fifth bulleted paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) "b" must also have experience in administering dosages

in the same dosage category or categories (i.e., 41.2(69) “b”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

- Reserved.

● Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this bulleted paragraph. Radioactive drugs containing radionuclides in categories not included are regulated under 41.2(88). This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

- Oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required;
- Oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);
- Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emissions, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69) “b”(1) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 41.2(37) for which the individual is requesting authorized user status. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75) or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(69) “b”(1).

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) or quantities greater than 33 millicuries (1.22 gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) Training for use of manual brachytherapy sources. Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate

Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility authorized to use byproduct materials under 41.2(43), involving:

• Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and
- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70) “*b*”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(70) “*b*”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 41.2(43). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(70), 41.2(75), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(70) “*b*”(1) and (2).

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70) or equivalent NRC or agreement state requirements; or

b. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and
- (2) Has completed supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
 1. Examination of each individual to be treated;
 2. Calculation of the dose to be administered;
 3. Administration of the dose; and
 4. Follow-up and review of each individual's case history; and
- (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), 41.2(71) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71) "b"(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

- a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72) "c" and "d" and whose certification has been recognized by the NRC or an agreement state. The names of the board certificates that have been recognized by the NRC or agreement state must be posted on the NRC's Medical Uses Licensee Toolkit web page; or
- b. Is an authorized user for uses listed in 41.2(33) or equivalent NRC or agreement state requirements; or
- c. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
- d. Has completed training in the use of the device for the uses requested.

41.2(73) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized under 41.2(49) to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in 41.2(73) "c." The names of board certification that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - (1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
 - (2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or
- b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 1. 200 hours of classroom and laboratory training in the following areas:
 - Radiation physics and instrumentation;
 - Radiation protection;
 - Mathematics pertaining to the use and measurement of radioactivity; and
 - Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements at a medical facility that is authorized to use byproduct material in 41.2(49), involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)“b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)“b”(1) and (2) and 41.2(73)“c” and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(73), 41.2(75), or equivalent NRC or agreement state requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(73)“b”(1) and (2); and

c. Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

41.2(74) Training for an authorized medical physicist. Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)“c.” The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC’s Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized under this rule by the NRC or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), 41.2(73), or 41.2(75); and

(3) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

b. (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74) "b"(1) and "c" and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

c. Has training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.

a. (1) An individual identified on an NRC or agreement state license, on a permit issued by the NRC or agreement state broad scope licensee, on a master material license permit, or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before July 22, 2020, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78), respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in 41.2(65) "d" or 41.2(74) "c," as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in comprehensive health physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 41.2(65) to be identified as a radiation safety officer or as an associate radiation safety officer on an NRC or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 41.2(74), for those materials and uses that these individuals performed on or before October 24, 2005.

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before July 22, 2020, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material issued by the NRC or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized on or before October 24, 2005, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

1. For uses authorized under 41.2(31) or 41.2(33), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

2. For uses authorized under 41.2(37), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

3. For uses authorized under 41.2(43) or 41.2(49), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

4. For uses authorized under 41.2(41), a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this rule.

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

41.2(76) Reserved.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), 41.2(85), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4. Using administrative controls to avoid medical events in the administration of byproduct material; and

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78) "b" and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

41.2(79) and 41.2(80) Reserved.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81) "c" (1) and (2) and whose certification process has been recognized by the NRC or an agreement state. The names of the board certifications that have been recognized by the NRC or agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under 41.2(69) "a" or "b" for uses in the oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or 41.2(82) or equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) "a" or "b," 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69) "b" must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81) "c" (1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized under 41.2(37). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally as specified in 41.2(69) "b" (1) "2," seventh bulleted paragraph; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(81) "c" (1) and (2).

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee

shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)“c”(1) and (2), and whose certification has been recognized by the NRC or agreement state. The names of the board certifications that have been recognized by the NRC or agreement state must be posted on the NRC’s Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or meets equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)“c”(1) and (2) and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for medical uses authorized in 41.2(37). The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements and has experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(82), or equivalent NRC or agreement state requirements; has experience in administering dosages orally with greater than 33 millicuries of sodium iodide I-131, as specified in 41.2(69)“b”(1)“2,” seventh bulleted paragraph; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(82)“c”(1) and (2).

41.2(83) *Provisions for the protection of human research subjects.*

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) Calibration measurements of brachytherapy sources.

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84) "a."

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84) "a"(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84) "a" for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) Strontium-90 sources for ophthalmic treatment.

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 41.2(85) "b" are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

1. Is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an agreement state, permit issued by an NRC or agreement state broad scope medical use licensee, medical use permit issued by an NRC master material licensee, or permit issued by an NRC master material licensee broad scope medical use permittee; and

2. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

3. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4. Has documented training in:

- The creation, modification, and completion of written directives;
- Procedures for administrations requiring a written directive; and
- Performing the calibration measurements of brachytherapy sources as detailed in 41.2(84).

b. The individuals who are identified in 41.2(85) "a" must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84); and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 41.2(85) "a" will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

c. A licensee shall retain a record of the activity of each strontium-90 source for the life of the source. The record must include:

(1) The date and initial activity of the source under 41.2(84); and

(2) For each decay calculation, the date and the source activity as determined under this subrule.

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

b. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of sodium iodide I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose;

(6) For permanent implant brachytherapy:

1. Before implantation: the treatment site, the radionuclide, and the total source strength; and

2. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(7) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radionuclide, and dose; and

2. After implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or, equivalently, the total dose), and date;

(8) For therapeutic use of radiation machines, see 41.3(14).

c. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

d. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives.

e. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41.

f. Determine if a reportable medical event, as described in 641—38.2(136C), has occurred.

g. Determine, for a permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the postimplantation portion of the written directive, unless a written justification of patient unavailability is documented.

h. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

i. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

41.2(88) *Other medical uses of byproduct material or radiation from byproduct material.* A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C) (e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) *Training for the parenteral administration of unsealed byproduct material requiring a written directive.*

a. Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

(1) Is an authorized user under 41.2(69) for parenteral administration uses listed in 41.2(69) "b"(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

(2) Is an authorized user under 41.2(70) or 41.2(73) or equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89) "b"; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73) and who meets the requirements in 41.2(89) "b";

or

b. The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 41.2(69) “b”(1)“2,” seventh bulleted paragraph. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements, in the parenteral administration listed in 41.2(69) “b”(1)“2,” seventh bulleted paragraph. A supervising authorized user who meets the requirements in 41.2(69), 41.2(89), or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
5. Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration as specified in 41.2(69) “b”(1)“2,” seventh bulleted paragraph; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89) “b”(1) or (2), and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), 41.2(89) or equivalent NRC or agreement state requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(89), or equivalent NRC or agreement state requirements; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 41.2(89) “b”(1) and (2).

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641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

“*Accessible surface*” means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

“*Added filtration*” means any filtration which is in addition to the inherent filtration.

“*Beam-limiting device*” means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

“*Beam-scattering foil*” means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

“*Bent beam linear accelerator*” means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

“*Contact therapy system*” means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

“*Dose monitor unit (DMU)*” means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

“*External beam radiation therapy*” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“*Field flattening filter*” means a filter used to homogenize the absorbed dose rate over the radiation field.

“*Filter*” means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

“*Gantry*” means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

“*Interruption of irradiation*” means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

“*Isocenter*” means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

“*Megavolt (MV) (mega electron volt (MeV))*” means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

“*Monitor unit (MU)*.” See “Dose monitor unit.”

“*Moving beam radiation therapy*” means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

“*Nominal treatment distance*” means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

“*Periodic quality assurance check*” means a procedure which is performed to ensure that a previous calibration continues to be valid.

“*Practical range of electrons*” corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in “Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25” (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, “Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV,” International Agency on Radiation Units and Measurements, September 15, 1984.

“*Radiation field.*” See “Useful beam.”

“*Radiation head*” means the structure from which the useful beam emerges.

“*Radiation therapy physicist*” means an individual qualified in accordance with 41.3(6).

“*Redundant beam monitoring system*” means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

“*Shadow tray*” means a device attached to the radiation head to support auxiliary beam blocking material.

“*Stationary beam radiation therapy*” means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

“*Target*” means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

“*Tenth-value layer (TVL)*” means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

“*Therapeutic radiation machine*” means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

“*Virtual source*” means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 641—39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant’s agent shall ensure that the requirements of 641—41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

- (1) Radiology or therapeutic radiology by the American Board of Radiology; or
- (2) Radiation oncology by the American Osteopathic Board of Radiology; or
- (3) Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
- (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5) “*b*” above, the classroom and laboratory training shall include:

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of ionization radiation; and
- (4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4) “*b*” above, training shall be under the supervision of an authorized user and shall include:

- (1) Reviewing the full calibration measurements and periodic quality assurance checks;
- (2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;
- (3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5) "b," the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

(5) Therapeutic medical physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Physicists in Medicine; or

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16) "a," 41.3(17) "c" and "d," and 41.3(18) "e" and "f" under the supervision of a radiation therapy physicist during the year of work experience.

41.3(7) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 42. The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

- a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;
- b. The visiting authorized user meets the requirements of 41.3(5); and
- c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

- a. Report of acceptance testing;
- b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 641—41.3(136C), as well as the name(s) of person(s) who performed such activities;
- c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;
- d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
- e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 641—41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Reserved.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and
2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;
- (4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and
- (5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or
2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;
2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

- (1) The registrant's name;
- (2) The name of the prescribing physician;
- (3) A brief description of the event;
- (4) Why the event occurred;
- (5) The effect, if any, on the individual or individuals who received the misadministration;
- (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
- (7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that

individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

- (1) The registrant's name and the names of the individuals involved;
- (2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;
- (3) A brief description of the event; why it occurred; and the effect, if any, on the individual;
- (4) The actions, if any, taken or planned to prevent recurrence; and
- (5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and
2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1) "a" and "b."

(2) In addition to the requirements of 41.3(16) "a"(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;
2. After making any change in the location of the therapeutic radiation machine within the treatment room;
3. After relocating the therapeutic radiation machine; or
4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16) "a"(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16) "a"(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.
 - b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)“a” indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1)“a” and “b,” before beginning the treatment program the registrant shall:
 - (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)“a” and “b”;
 - (2) Perform the survey required by 41.3(16)“a” again; and
 - (3) Include in the report required by 41.3(16)“d” the results of the initial survey, a description of the modification made to comply with 41.3(5)“b”(1), and the results of the second survey; or
 - (4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1)“a” and “b.”
 - c. Dosimetry equipment.
 - (1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.
 1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.
 2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.
 - (2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)“c”(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)“c”(1).
 - (3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)“c”(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.
 - d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)“a” and “b” to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

 - a. Equipment requirements.
 - (1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:
 1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.
 2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.
 3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)“a”(1)“1” and 41.3(17)“a”(1)“2” for the

specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. Means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;
2. There shall be an indication at the control panel identifying which X-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 41.3(17) "b"(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
2. At intervals not exceeding one year; and
3. Before medical use under the following conditions:
 - Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
 - Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
4. Notwithstanding the requirements of 41.3(17) "c"(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17) "b"(3).

(2) To satisfy the requirement of 41.3(17) "c"(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17) "d"(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17) "c"(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17) "c"(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17) "c"(1);

(5) The registrant shall use the dosimetry system described in 41.3(16) "c"(2) to make the quality assurance check required in 41.3(17) "d";

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17) "d"(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17) "d"(6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17) "d"(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17) "d"(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine,

the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)“a”(9)“5”;

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17)“c” and “d” have been met.

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18)“a”(1)“1,” the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)“a”(1)“1” to “3” for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the

area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)“a”(9) relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use “no filter” has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use; and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;

- Have only one scale and no electrical or mechanical scale multiplying factors;

- Utilize a design such that increasing dose is displayed by increasing numbers; and

- In the event of power failure, the beam monitoring information required in 41.3(18)“a”(6)“4” displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)“a”(7)“1” shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18)“a”(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18) "a"(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and
3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
2. The mode of operation shall be displayed at the treatment control panel;
3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)“a”(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 641—41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1) "a" and "b," interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18) "a"(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18) "e" and protection surveys required by 41.3(16) "a";

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18) "f"(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18) “d” shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16) “a,” 41.3(18) “e,” and 41.3(18) “f” have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Acceptance testing, commissioning, and full calibration measurements.

(1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Acceptance testing and commissioning shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45, and the manufacturer’s contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18) “e”(1)“3.”

(2) The registrant shall use the dosimetry system described in 41.3(16) “c” to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)“f”(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)“c”(1) to make the periodic quality assurance checks required in 41.3(18)“f”(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)“f”(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week or at longer intervals as recommended by the manufacturer;

(7) To satisfy the requirement of 41.3(18)“f”(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the “BEAM-ON,” interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(8) Reserved.

(9) The registrant shall promptly repair any system identified in 41.3(18)“f”(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)“f”(1) and 41.3(18)“f”(7) for three years. The record shall include the date of the quality assurance check, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the manufacturer’s name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved

for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 641—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

[ARC 0577C, IAB 2/6/13, effective 3/13/13; ARC 1639C, IAB 10/1/14, effective 11/5/14]

641—41.4 and 41.5 Reserved.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

“*Accreditation body*” means an entity that has been approved by FDA to accredit mammography facilities.

“*Action limits*” or “*action levels*” means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

“*Adverse event*” means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;

2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

3. Use of personnel who do not meet the applicable requirements of this chapter.

“*Air kerma*” means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

“*Annually*” means within 10 to 14 months of previous occurrence.

“*Artifact*” means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

“Automatic exposure control systems” means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

“Average glandular dose” means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: “Dose.”

“Breast implant” means a prosthetic device implanted in the breast.

“Calendar quarter” means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

“Category 1” means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

“Certificate” means the certificate described in 41.6(2)“a”(2).

“Certification” means the process of approval of a facility by the FDA or this agency to provide mammography services.

“Clinical image” means a mammogram.

“Compression device” means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

“Computed radiography mammography” means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

“Consumer” means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

“Contact hour” means an hour of training received through direct instruction.

“Continuing education unit” or *“continuing education credit”* means one contact hour of training.

“Craniocaudal view” means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

“Dedicated mammography equipment” means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

“Direct detector technology” means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

“Direct instruction” means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or
2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

“Direct supervision” means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient’s records; or
2. During the performance of a mammography examination or survey of the facility’s equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the

performance of the individual being supervised who is performing the examination or conducting the survey.

“*Dose*” means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

“*Exposure*” means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen= $2.58 \times 10E-4$ Coulombs of charge per kilogram of air.

“*Facility*” means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

“*FDA*” means the Food and Drug Administration.

“*First allowable time*” means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The “first allowable time” may vary with the certifying body.

“*Full field digital mammography*” means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

“*Grids*” means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

“*Image noise.*” See “Radiographic noise.”

“*Image receptor support device*” means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

“*Interpreting physician*” means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)“a.”

“*Kerma*” means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

“*Laterality*” means the designation of either the right or left breast.

“*Lead interpreting physician*” means the interpreting physician assigned the general responsibility for ensuring that a facility’s quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

“*Mammogram*” means a radiographic image produced through mammography.

“*Mammographic modality*” means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

“*Mammography*” means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or
3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

“*Mammography equipment evaluation*” means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

“Mammography medical outcomes audit” means a systematic collection of mammography results and the comparison of those results with outcomes data.

“Mammography unit(s)” means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

“Mean optical density” means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

“Medical physicist” means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)“c.”

“Mediolateral view” means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

“MQSA” means the Mammography Quality Standards Act of 1992.

“Multi-reading” means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“Oblique mediolateral view” means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

“Patient” means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

“Phantom” means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

“Phantom image” means a radiographic image of a phantom.

“Physical science” means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

“Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”

“Provisional certification” means the six-month certification time period in which a facility has to complete the accreditation/certification process.

“Qualified instructor” means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers’ representatives.

“Quality control technologist” means an individual meeting the requirements of 41.6(5)“a”(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

“Radiographic equipment” means X-ray equipment used for the production of static X-ray images.

“*Radiologic technologist*” means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)“b.”

“*Radiologist continuing experience*” means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

“*Reinstatement*” means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

“*Screen-film mammography*” means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

“*Screening mammography*” means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

“*Serious adverse event*” means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

“*Serious complaint*” means a report of a serious adverse event.

“*Standard breast*” means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

“*Supplier*” means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

“*Survey*” means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

“*Time cycle*” means the film development time.

“*Traceable to a national standard*” means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

“*Written report*” means interpreting physician’s technical narrative of a mammography evaluation.

“*Written statement*” means interpreting physician’s description of a mammography examination written in lay terms.

41.6(2) Registration and application standards and requirements.

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

c. Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a “negative” or “benign” examination.

(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)“f”(1).

(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)“b”(2).

(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)“f”(3).

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

h. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

i. Soft copy review workstation requirements.

(1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two monitors that meet one of the following criteria:

1. Have 5 megapixel resolution; or
2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer’s quality control manual or that outlined by the image receptor manufacturer’s designated soft copy review workstation quality control manual.

41.6(3) Mammography personnel. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. *Interpreting physicians.* All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)“a”(3)“1” applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;
2. Either:
 - Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or
 - Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)“a”; and

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)“a”(3)“2” applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in

the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“a”(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)“a”(2)“2” even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)“a” or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)“a.” They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)“a”(1)“1” and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)“a”(1)“4.”

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)“a”(2)“1” shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician’s total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)“a”(4)“1” shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)“a”(2)“2” shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)“b” before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)“b”; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)“b”(3)“1” even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)“b”(3)“1” shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review

of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)“c”(2) shall meet the following:

- (1) Initial qualifications.
 1. Be Iowa approved; and
 2. Have a master’s degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;
 3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and
 4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or
- (2) Alternative initial qualifications.
 1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and
 2. Prior to April 28, 1999, have:
 - A bachelor’s degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.
 - Forty contact hours of documented specialized training in conducting surveys of mammography facilities.
 - Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
 - At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.
- (3) Continuing qualifications.
 1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)“c”(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.
 2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days shall be counted towards this requirement.
 3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.
- (4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified

medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) Obtaining and preserving records.

a. The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

- (1) The date the mammography procedure was performed.
- (2) The date of the interpretation.
- (3) The name of the interpreting physician.
- (4) The name of the patient and an additional patient identifier.
- (5) A description of the procedures performed.
- (6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(10) Information on a patient's breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4) "e"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

(3) The breast density information as designated in the report pursuant to 41.6(4) "b"(10) shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the notification to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography and shall be stated in language appropriate for the facility's patient population.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4) "b," to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) Quality assurance program.

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5) "e" through "k."

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film-screen mammography shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

- (3) Output reproducibility and linearity.
- (4) Automatic exposure control reproducibility and linearity.
- (5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

- (1) Processor performance shall be accomplished daily before processing patient films.
- (2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.
- (3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5) "k." If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

h. Retake analysis program—film-screen and full field digital.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be below plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.

4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.

- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.

- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.

- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

- Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.

- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5) “k”(5)“6.”

(7) Use of test results.

1. After completion of the tests specified in 41.6(5) “k,” the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer’s recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5) “k.”

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer’s quality control manual or in accordance with the appropriate FDA-approved alternative requirements.

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5) “k”(5) and (6), the weekly phantom image quality test described in 41.6(5) “k”(2) and the quarterly retake analysis results described in 41.6(5) “h.”

2. The results of all tests conducted by the facility in accordance with 41.6(5) “k”(1) through (7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer’s quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must

be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) Equipment standards. The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for “spot compression”), may be provided. Such compression paddles for special purposes are not subject to 41.6(6) “i”(6) and (7).

(4) Except as provided in 41.6(6) “i”(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliamperere seconds (mAs) or at least one of its component parts (milliamperere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans—film-screen.

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

u. Mobile units and vans—full field digital. Appropriate manufacturer’s quality control manual procedures and criteria shall be met.

41.6(7) Safety standards for mammography equipment.

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall be monitored in accordance with 641—40.37(136C).

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

HVL	Mo/Mo Target Filter X-Ray Voltage (kVp)											W/AI Target Filter Combination	
	23	24	25	26	27	28	29	30	31	32	33		
0.23	109												
0.24	113	116											
0.25	117	120	122										
0.26	121	124	126	128									
0.27	126	128	130	132	134								
0.28	130	132	134	136	138	139							
0.29	135	137	139	141	142	143	144						
0.30	139	141	143	145	146	147	148	149					170
0.31	144	146	147	149	150	151	152	153	154				175
0.32	148	150	151	153	154	155	156	158	159	160	160		180
0.33	153	154	155	157	158	159	160	162	163	164	164		185
0.34	157	159	160	161	162	163	164	166	167	168	168		190
0.35		163	164	166	167	168	169	170	171	172	172		194
0.36			168	170	171	172	173	174	175	176	176		199
0.37				174	175	176	177	178	178	179	180		204
0.38					179	180	181	182	182	183	184		208
0.39						184	185	186	186	187	188		213
0.40							189	190	191	192	192		217
0.41								194	195	196	196		221
0.42										200	200		225
0.43											204		230
0.44													234
0.45													238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of $(0.50 \text{ R}) \times (174 \text{ mrad/R}) = 87 \text{ mrad}$ or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/AI conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.

RULE 641—41.6(136C)—APPENDIX I
Rescinded IAB 4/5/00, effective 5/10/00

RULE 641—41.6(136C)—APPENDIX II

Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure

4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

[ARC 1401C, IAB 4/2/14, effective 5/7/14; ARC 3393C, IAB 10/11/17, effective 11/15/17]

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) Definitions. In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

“*Collaborative setting*” means a setting in which a qualified radiologist and surgeon (under 41.7(3) “a” or 41.7(3) “c”) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient’s benefit.

“*Procedure*” means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

“*Qualified training physician*” means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

“*Stereotactically guided breast biopsy*” means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

“*Supervising physician*” means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) Registration and application standards and requirements.

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial, suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the

public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is revoked, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) Physicians. Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)“*a.*”

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3)“*a*”(1)“2” above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year. If experience is not maintained, the physician must requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)“a.”

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)“c”) performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years’ experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.
8. Must be responsible for post-biopsy management of the patient.
- (2) Maintenance of proficiency and CME requirements.
 1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”
 2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.
 3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.
 4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

41.7(4) Medical physicist.

- a. Must be qualified according to 41.6(3)“c.”
- b. Must have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)“a” and 41.7(4)“b.”
- c. Maintenance of proficiency and continuing education requirements.
 - (1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and
 - (2) Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

41.7(5) Radiologic technologist.

- a. Must be qualified according to 41.6(3)“b.”
- b. Must meet the following initial requirements:
 - (1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).
 - (2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.
- c. Maintenance of proficiency and continuing education and experience requirements.
 - (1) Following the first anniversary in which the requirements of this subrule were met, have performed at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).
 - (2) Following the third anniversary in which the requirements of this subrule were met, have at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.
 - (3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)“b”(4)“1.”

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

- (1) The date of the procedure.
- (2) The name of the patient and one additional patient identifier.
- (3) The name of the radiologic technologists and physicians performing the procedure.
- (4) A description of the service provided.
- (5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

- (1) Quality assurance activities including the medical audit,
- (2) Oversight of the quality control program, and
- (3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

• Digital – X-ray field must not extend beyond the image receptor by more than 5 mm on any side.

• Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.

• Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

• Digital – Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.

• Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.
 - Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.
 - Failures must be corrected before further procedures are performed.
9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.
10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.
11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test “lesion” in the sample chamber. Failures must be corrected before further procedures are performed.
- (2) Analyzing the monitoring results to determine if there are any problems requiring correction.
- (3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.
- e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:
- (1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.
- (2) Visual checklist (monthly). Any failed items must be corrected within 30 days.
- (3) Phantom image (weekly). Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures must be corrected before further procedures are performed.
- (4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.
- (5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.
- f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.
- g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).

41.7(8) Equipment standards.

- a. Be specifically designed for stereotactically guided breast biopsy.
- b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) Safety standards.

- a.* Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.
- b.* Equipment operators shall wear personnel monitors to monitor their radiation exposure.
- c.* Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.
- d.* Equipment shall be shockproof and grounded to protect against electrical hazards.
- e.* Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

[ARC 1401C, IAB 4/2/14, effective 5/7/14]

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN
OPERATOR'S BOOTH1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m²).

(2) Regardless of size or shape, at least 0.09 m² (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS
PROPOSING TO CONDUCT HEALING
ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.

3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the X-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the X-ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.

17. The dates of the screening to include beginning and ending dates.

18. A copy of IRB for a research project or information justifying the research project.

CHAPTER 41—APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance ^a
Daily	<u>Dosimetry</u>	
	X-ray output constancy	3%
	Electron output constancy ^b	3%
	<u>Mechanical</u>	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	<u>Safety</u>	
	Door interlocks	functional
	Audiovisual monitors	functional
	Monthly	<u>Dosimetry</u>
X-ray output constancy ^c		2%
Electron output constancy ^c		2%
Backup monitor constancy		2%
X-ray central axis dosimetry parameter (PDD, TAR) constancy		2%
Electron central axis dosimetry parameter constancy (PDD)		2mm @ therapeutic depth
X-ray beam flatness constancy		2%
Electron beam flatness constancy		3%
X-ray and electron symmetry		3%
<u>Safety Interlocks</u>		
Wedge, electron cone interlocks		functional
<u>Mechanical</u>		
Light/radiation field coincidence		2mm or 1% on a side ^d
Gantry/collimator angle indicators		1 degree
Wedge position		2mm (or 2% change in transmission factor)
Tray position		2mm
Applicator position		2mm
Field size indicators		2mm
Cross-hair centering		2mm diameter
Treatment couch position indicators		2mm/1deg
Latching of wedges, blocking tray	functional	
Jaw symmetry ^e	2mm	
Field Light intensity	functional	
Annual	<u>Dosimetry</u>	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

^b All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

^c A constancy check with a field instrument using temperature pressure corrections.

^d Whichever is greater. Should also be checked after change of light field source.

^e Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance ^a
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy ^f	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	<u>Safety Interlocks</u>	
	Follow manufacturer's test procedures	functional
	<u>Mechanical</u>	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

^f Most wedges' transmission factors are field size and depth dependent.

^a The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values \pm the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

CHAPTER 41—APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED
FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and “allowed” radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, “Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV” (1976).

B. NCRP Report 51, “Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities” (1977).

C. NCRP Report 79, “Neutron Contamination from Medical Electron Accelerator” (1984).

D. NCRP Report 144, “Radiation Protection for Particle Accelerator Facilities” (2003).

These rules are intended to implement Iowa Code chapter 136C.

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 [Filed ARC 0577C (Notice ARC 0381C, IAB 10/3/12), IAB 2/6/13, effective 3/13/13]
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[◇] Two or more ARCs

CHAPTER 45
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL
RADIOGRAPHIC OPERATIONS, PARTICLE ACCELERATORS FOR NONHUMAN USE,
ANALYTICAL X-RAY EQUIPMENT, AND WELL-LOGGING

[Prior to 8/5/92, see 641—41.4(136C)]

641—45.1(136C) General requirements for industrial radiography operations.

45.1(1) Purpose and scope.

a. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 22, 2020.

45.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply. As used in this chapter, the following definitions apply:

“*Annual refresher safety training*” means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

“*Associated equipment*” means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control (drive) cable, removable source stop, “J” tube and collimator when it is used as an exposure head.

“*Cabinet X-ray system*” means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X-ray system is intended to:

1. Contain at least that portion of a material being irradiated;
2. Provide radiation attenuation; and
3. Exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

“*Certifiable cabinet X-ray system*” means an existing uncertified X-ray system that has been modified to meet certification requirements specified in 21 CFR 1020.40.

“*Certified cabinet X-ray system*” means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

“*Certifying entity*” means an independent certifying organization meeting the requirements of Appendix A in 10 CFR Part 34 or an agreement state meeting the requirements in Appendix A, Parts II and III of 10 CFR Part 34.

“*Collimator*” means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

“*Control (drive) cable*” means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

“*Control drive mechanism*” means a device that enables the source assembly to be moved to and from the exposure device.

“*Control tube*” means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

“*Crank-out device*” means the cable, protective sheath, and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

“*Enclosed radiography*” means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded-room radiography.

“*Exposure head*” means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

“*Field station*” means a facility where licensed material may be stored or used and from which equipment is dispatched.

“*Fluoroscopic imaging assembly*” means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

“*GED*” means general educational development.

“*Guide tube (projection sheath)*” means a flexible or rigid tube (i.e., “J” tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

“*Hands-on experience*” means experience in all of those areas considered to be directly involved in the radiography process.

“*I.D. card*” means the document issued by the agency, another agreement state, a licensing state, or third-party certification to industrial radiographers following completion of requirements stated in 45.1(10)“b.”

“*Independent certifying organization*” means an independent organization that meets all of the criteria of Appendix A in 10 CFR Part 34.

“*Lay-barge radiography*” means industrial radiography performed on any water vessel used for laying pipe.

“*Lixiscope*” means a portable light-intensified imaging device using a sealed source.

“*Lock-out survey*” means a radiation survey performed to verify that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or when securing the radiographic exposure device or source changer.

“*Minimal threat*” means that during the operations of electronic devices capable of generating or emitting fields of radiation:

1. No deliberate exposure of an individual occurs;
2. The radiation is not emitted in an open beam configuration; and
3. No known physical injury to an individual has occurred.

“*Offshore*” means within the territorial waters of the United States.

“*Offshore platform radiography*” means industrial radiography conducted from an offshore platform over a body of water.

“*Permanent radiographic installation*” means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

“*Practical examination*” means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

“*Radiation safety officer*” means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 45.1(10)“d.”

“*Radiographer*” means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)“b,” who performs or personally supervises industrial radiographic operations, and is responsible to the licensee or registrant for ensuring compliance with the requirement of these rules and all license and certificate of registration conditions.

“*Radiographer certification*” means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

“*Radiographer’s assistant*” means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)“a” and who uses sources of radiation and related handling tools or radiation survey instruments under the direct supervision of a radiographer trainer.

“*Radiographer trainer (instructor)*” means any individual who instructs and supervises radiographer’s assistants during on-the-job training and who meets the requirements of 45.1(10)“c.”

“*Radiographic exposure device*” (also called a camera or a projector) means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure, or any other X-ray industrial system whereby a permanent or semipermanent image is recorded on an image receptor by action of ionizing radiation.

“*Radiographic operations*” means all activities associated with the presence of radioactive sources or radiation in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

“*Radiographic personnel*” means any radiographer or radiographer’s assistant.

“*Residential location*” means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

“*Shielded position*” means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

“*Shielded-room radiography*” means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

“*Source assembly*” means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

“*Source changer*” means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

“*Source container*” means a shielded device in which sealed sources are secured, transported, and stored.

“*Storage area*” means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

“*Storage container*” means a container in which sealed sources are secured and stored.

“*S-tube*” means a tube through which the radioactive source travels when inside a radiographic exposure device.

“*Temporary job site*” means any location where radiographic operations are conducted and where licensed material may be stored other than the location(s) listed in a specific license or certificate of registration.

“*Trainee status card*” means the document issued by the agency following completion of the requirements of 45.1(10)“a”(1) and (2).

“*Transport container*” means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

“*Underwater radiography*” means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

45.1(3) Exemptions.

a. Uses of certified and certifiable cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this chapter, except for the requirements of 45.2(6)“b” and “c.”

b. Industrial uses of lixiscopes are exempt from the requirements in this chapter.

c. Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with 641—subrule 38.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

45.1(4) Receipt, transfer, and disposal of sources of radiation. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sealed sources and devices using DU for shielding and machine-produced sources of radiation. These records shall include the date, the name of the individual making the record, the radionuclide, number of curies or mass (for DU), and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for three years after they are made.

45.1(5) Radiation survey instruments.

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and 641—subrule 40.36(1). Instrumentation required by this subrule shall have a range such that 2 millirems (0.02 millisievert) per hour through 1 rem (0.01 sievert) per hour can be measured.

b. Notwithstanding the requirements of 641—subrule 40.36(3) each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed six months and after each instrument servicing;

(2) Such that accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked;

(3) At 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at 3 points between 2 and 1000 mrem per hour for digital instruments; and

(4) By a person licensed or registered by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission to perform such service.

c. Records of these calibrations shall be maintained for three years after the calibration date for inspection by the agency.

d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

45.1(6) Quarterly inventory. Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for three years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

45.1(7) Utilization logs.

a. Each licensee shall maintain utilization logs of the use of each sealed source. The logs shall include:

(1) A unique description, which includes the make, model, and serial number of each radiographic exposure device containing a sealed source or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom the sealed source is assigned;

(3) The plant or site where each sealed source is used and the date of use; and

(4) The date(s) each sealed source is removed from storage and returned to storage.

b. Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each source of radiation;

(2) The identity of the radiographer using the source of radiation;

(3) The date(s) each source of radiation is energized or used and the number of exposures made.

c. Utilization logs may be kept on clear, legible records containing all the information required by 45.1(7) “a” or “b.” Copies of utilization logs shall be maintained for agency inspection for three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

45.1(8) *Inspection and maintenance.*

a. Each licensee or registrant shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means.

b. Each licensee or registrant shall have written procedures and conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, source changers, survey instruments, and associated equipment to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer’s specifications. Replacement components shall meet design specifications. This program shall cover, as a minimum, the items in Appendix B of this chapter.

c. Each licensee shall have a program and written procedures for the inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The program must include procedures to ensure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

d. If equipment problems are found, the equipment must be removed from service until repaired.

e. The record of equipment problems and of any maintenance performed under 45.1(8) must be retained for three years after the record is made. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair or maintenance, if any, was performed.

45.1(9) *Permanent radiographic installations.* Permanent radiographic installations having high radiation area entrance controls of the type described in 641—paragraphs 40.42(1) “b” and “c” shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for three years from the date of the event.

45.1(10) *Training and testing for radiographic personnel.*

a. Radiographer’s assistant requirements. No licensee or registrant shall permit any individual to act as a radiographer’s assistant, as defined in this chapter, until:

(1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:

1. The subjects outlined in Appendix A, presented in a 40-hour course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

2. The rules contained in this chapter and the applicable sections of 641—Chapter 38, the applicable U.S. Department of Transportation and NRC transportation regulations in 641—Chapter 39, and 641—Chapter 40;

3. The appropriate conditions of license(s) or certificate(s) of registration;

4. The licensee’s or registrant’s operating and emergency procedures;

5. And developed competence to use, under the personal supervision of the radiographer, the licensee’s or registrant’s radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use;

6. And has demonstrated competence in the use of radiographic exposure devices, sources, survey instruments and associated equipment described in 45.1(10)“a”(1) by successful completion of a practical examination covering this material.

(2) The individual possesses a current agency-issued trainee status card issued after completion of 45.1(10)“a”(1). Trainee status will be granted only once for each individual and is valid for no longer than two years.

b. Radiographer requirements. No licensee or registrant shall permit any individual to act as a radiographer:

(1) Until it has been documented to the agency that such individual:

1. Has completed the requirements of 45.1(10)“a”(1);

2. Has completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines, or both. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (three months or 480 hours). Active participation does not include safety meetings or classroom training;

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments by successful completion of a practical examination covering this material;

(2) Unless the individual has successfully completed within the last five years the appropriate agency-administered examination prescribed in 45.1(10)“f”(2) or equivalent examination; and

(3) Unless the individual possesses a current I.D. card.

c. Radiographer trainer. No individual shall act as a radiographer trainer unless such individual:

(1) Has met the requirements of 45.1(10)“a”(1) and “b”;

(2) Has one year of documented experience as an industrial radiographer and possesses a current ID card issued at least one year prior to the application for a trainer card; and

(3) Is named on the specific license or certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer, or

(4) Possesses a valid radiographer trainer card issued by the agency.

d. Radiation safety officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee’s program.

(1) A radiation safety officer (RSO) shall be designated for every industrial radiography license and certificate of registration issued by the agency.

(2) The RSO’s qualifications shall include:

1. Possession of a high school diploma or a certificate of high school equivalency based on the GED test;

2. Completion of the training and testing requirements of 45.1(10)“a”(1) and 45.1(10)“b”(1)“3,” (2), and (3);

3. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

4. Formal training in the establishment and maintenance of a radiation protection program.

The agency will consider alternatives when the RSO has either appropriate training or experience, or both, in the field of ionizing radiation and, in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(3) The specific duties of the RSO include, but are not limited to, the following:

1. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

2. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

3. To ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

4. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

5. To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

6. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

7. To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

8. To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

9. To maintain records as required by these rules (see Appendix C);

10. To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

11. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.2(3), and 45.3(6) “b”;

12. To ensure that personnel are complying with these rules, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant; and

13. To ensure that annual refresher safety training has been provided for each radiographer and radiographer’s assistant at intervals not to exceed 12 months.

e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10) “a” and “b” are met. Records of training for all industrial radiographic personnel must include personnel certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations. Records of annual refresher training and semiannual inspection of job performance for all industrial radiographic personnel must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any noncompliances observed by the RSO. Records shall be maintained until disposal is authorized by the agency. The agency shall not release records for disposal unless the records have been maintained at least three years.

f. Applications and examinations.

(1) Application.

1. An application for taking the examination shall be on forms prescribed and furnished by the agency along with the fee required in 641—subrule 38.8(3). The application shall be submitted only after the training requirements of 45.1(10) “a” and “b” have been completed.

2. An individual whose I.D. card has been suspended or revoked shall obtain prior approval from the agency to apply to take the examination.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at such times and places as the agency shall determine. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will emphasize the applicant’s ability to safely use sources of radiation and related equipment and the applicant’s knowledge of these rules.

2. A candidate failing an examination may apply for reexamination in accordance with 45.1(10) “f”(1) and will be reexamined. A candidate shall not retake the same version of the agency-administered examination.

3. The examination will be held at locations designated by the agency. The examination shall normally be offered quarterly. Dates, times, and locations of the examinations will be provided by the agency.

4. The examination will be in the English language.

5. To take the examination, an individual shall have a picture identification card (such as an Iowa driver's license) at the time of the examination.

6. Calculators will be permitted during the examination; however, calculators or computers with preprogrammed data or formulas, including exposure calculations, will not be permitted.

7. The examination will be a "closed book" examination.

8. Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to the administration is prohibited.

9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual may resubmit an application and an additional examination fee to take the examination not earlier than three months later.

10. The names and scores of individuals taking the examination shall be a public record.

g. Identification procedures.

(1) I.D. card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10) "b" and the examination prescribed in 45.1(10) "f"(2) or an equivalent examination.

2. Each person's I.D. card shall contain the person's photograph.

3. The I.D. card remains the property of the state of Iowa and may be revoked or suspended under the provisions of 45.1(10) "h."

4. Any individual who wishes to replace the I.D. card shall submit to the agency a written request for a replacement I.D. card, stating the reason a replacement I.D. card is needed and the fee required in 641—subrule 38.8(3). The individual shall maintain in possession a copy of the request while performing industrial radiographic operations until a replacement I.D. card is received from the agency.

(2) Expiration of I.D. card. Each I.D. card expires at the end of the day, in the month and year stated on the I.D. card.

(3) Renewal of I.D. card.

1. Applications for examination to renew an I.D. card shall be filed in accordance with 45.1(10) "f"(1).

2. The examination for renewal of an I.D. card shall be administered in accordance with 45.1(10) "f"(2).

3. A renewed I.D. card shall be issued in accordance with 45.1(10) "g"(1).

h. Revocation or suspension of an I.D. card.

(1) Any radiographer who violates these rules may be required to show cause at a formal hearing why the I.D. card should not be revoked or suspended.

(2) When an agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending the I.D. card, the industrial radiographer shall surrender the I.D. card to the agency until such time as the order is changed or the suspension expires.

(3) An agency's inspector may, in certain instances, confiscate any radiographer's I.D. card on the spot while conducting an inspection or investigation. If the inspector determines that the activities being conducted by the radiographer are significant enough to be classified as severity I, II, or III, as specified in 641—38.5(136C), and after obtaining the approval of agency management, the inspector may take any radiographer's I.D. card. The agency will then issue a cease and desist order to the radiographer's employer, forward the I.D. card(s) to the issuing entity, and notify the U.S. Nuclear Regulatory Commission and other agreement states.

i. Exemptions. Any person using a source of radiation to determine the presence of explosives in a package or the authenticity of a piece of art is exempt from the provisions of 45.1(10) "a" to "h."

j. Reciprocity.

(1) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category and class issued by a certifying entity as defined in 45.1(2).

2. The requirements and procedures of the certifying entity issuing the certification require the same or comparable certification standards as those required by 45.1(10)“a” through “e”; and

3. The individual submits a legible copy of the certification to the agency prior to entry into Iowa.

(2) Enforcement actions with the agency, another agreement state, or the U.S. Nuclear Regulatory Commission or any sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(3) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 45.1(10)“b.”

45.1(11) Internal audits. Except as provided in 45.1(11)“c,” the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer’s assistant to ensure that these rules, license requirements, and the licensee’s or registrant’s operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and radiographer’s assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or radiographer’s assistant has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or radiographer’s assistant must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can next participate in a radiographic operation.

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

d. Records of audits shall be maintained by the licensee or registrant for agency inspection for three years from the date of the audit.

45.1(12) Personnel monitoring control.

a. The personnel monitoring program shall meet the applicable requirements of 641—Chapter 40.

b. When performing industrial radiographic operations:

(1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer’s assistant, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically stimulated luminescent device (OSL device) or a thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

(2) Pocket dosimeters or electronic personal dosimeters shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 millirems. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(3) Pocket dosimeters or electronic personal dosimeters shall be recharged at the start of each work shift.

(4) Pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at the beginning and at the end of each work shift, and before each recharging.

(5) If an individual’s pocket dosimeter is discharged beyond its range (i.e., goes “off scale”), or if the electronic personal dosimeter reads greater than 200 millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual’s film badge, OSL device, or TLD shall be within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the

radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each individual monitoring device shall be assigned to and worn by only one individual.

(7) Film badges, OSL devices and TLDs must be replaced at least monthly.

(8) If an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the individual monitoring device. The results of the calculated exposure and the time period for which the individual monitoring device was lost or damaged must be included in the records maintained in 45.1(12)“c.”

c. Records of pocket dosimeter readings of personnel exposures and yearly operability checks required in 45.1(12)“d” shall be maintained for three years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained for three years after they are recorded. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges, OSLs, or TLDs, shall be maintained until the agency terminates the license.

d. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for three years from the date of the event.

e. Reports received from the film badge, OSL device or TLD processor shall be kept for inspection by the agency until the agency terminates the license.

f. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift. Records of alarm function checks shall be maintained for two years by the licensee or registrant for agency inspection;

(2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of the alarming ratemeter calibrations shall be maintained for three years by the licensee or registrant for agency inspection.

45.1(13) Supervision of radiographer's assistant. Whenever a radiographer's assistant uses radiographic exposure devices, sealed sources or associated equipment or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the direct supervision of a radiographer instructor. The direct supervision must include:

a. The radiographer's physical presence at the site where the source(s) of radiation is being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the radiographer's assistant's performance of the operations referred to in this subrule.

45.1(14) Access control.

a. During each industrial radiographic operation, a radiographer or radiographer's assistant shall maintain continuous, direct visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area or high radiation area, except at permanent radiographic installations where all entryways are locked to protect against unauthorized or accidental entry and the requirements of 45.1(9) are met.

b. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

45.1(15) Posting.

a. Notwithstanding any provisions in 641—subrule 40.62(1) areas in which radiography is being performed shall be conspicuously posted as required by 641—subrules 40.61(1) and 40.61(2).

b. Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate areas in accordance with 641—subrule 40.26(1) and to help prevent unauthorized entry.

c. During pipeline industrial radiography operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the radiation area.

d. Notwithstanding the requirements of 45.1(15)“a,” a restricted area may be established in accordance with 641—subrule 40.26(1) and may be posted in accordance with 641—subrules 40.61(1) and 40.61(2), i.e., both signs may be posted at the same location at the boundary of the restricted area.

45.1(16) Temporary job site requirements.

a. Documents and records. Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the agency:

- (1) Appropriate license or certificate of registration or equivalent document;
- (2) The appropriate operating and emergency procedures;
- (3) The applicable agency rules;
- (4) Survey records required pursuant to 45.2(5)“d” and 45.3(7)“j” for the period of operation at the site;
- (5) Daily pocket dosimeter records for the period of operation at the site;
- (6) The daily alarming ratemeter records for the period of operation at the site; and
- (7) The latest radiation survey instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter and decay charts for sources which have been manufactured within the last six months.

b. Reserved.

45.1(17) Specific requirements for radiographic personnel performing industrial radiography.

a. At a job site, the following shall be supplied by the licensee or registrant:

- (1) At least one operable, calibrated radiation survey instrument;
- (2) A current whole body personnel monitor (TLD, OSL device or film badge) for each individual;
- (3) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (5.16×10^{-5} C/kg) for each worker; and
- (4) An operable, calibrated alarm ratemeter for each worker; and
- (5) The appropriate barrier ropes and signs.

b. Each radiographer at a job site shall possess a valid I.D. card.

c. Each radiographer’s assistant at a job site shall possess a valid trainee status card issued by the agency.

d. Industrial radiographic operations shall not be performed if any of the items in 45.1(17)“a,” “b,” and “c” are not available at the job site or are inoperable.

e. No individual other than a radiographer or a radiographer’s assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

f. During an inspection by the agency, the agency inspector may terminate an operation if any of the items in 45.1(17)“a” are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

45.1(18) Notifications.

a. The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—40.95(136C) and 641—40.97(136C).

b. Each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:

- (1) The source assembly cannot be returned to the fully shielded position and properly secured;
- (2) The source assembly becomes disconnected from the drive cable;
- (3) The failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function; or
- (4) An indicator on a radiation-producing machine fails to show that radiation is being produced or an exposure switch fails to terminate production of radiation when turned to the off position.

c. The licensee or registrant shall include the following information in each report submitted in accordance with 45.1(18) “b”:

- (1) A description of the equipment problem;
- (2) Cause of each incident, if known;
- (3) Manufacturer and model number of equipment involved in the incident;
- (4) Location, time, and date of the incident;
- (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and
- (7) Names of personnel involved in the incident.

d. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year shall notify the agency prior to exceeding the 180 days.

45.1(19) Copies of operating and emergency procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license. Superseded material must be retained for three years after the change is made.

[ARC 8982B, IAB 8/11/10, effective 9/15/10; ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18; ARC 5059C, IAB 6/17/20, effective 7/22/20]

641—45.2(136C) Radiation safety requirements for the use of radiation machines in industrial radiography.

45.2(1) Locking of sources of radiation. The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.

45.2(2) Permanent storage precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

45.2(3) Requirements for radiation machines used in industrial radiographic operations.

a. Equipment used in industrial radiographic operations involving radiation machines manufactured after January 1, 1992, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976.

b. The registrant’s name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on all vehicles used to transport radiation machines for temporary job site use.

45.2(4) Operating and emergency procedures.

a. The registrant’s operating and emergency procedures shall include instructions in at least the following:

- (1) Operation and safety instruction on the radiation machine(s) to be used;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) The procedure for notifying proper personnel in the event of an accident;
- (8) Maintenance of records; and
- (9) Inspection and maintenance of radiation machines.

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a radiographer’s assistant, the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

d. Rescinded IAB 4/8/98, effective 7/1/98.

45.2(5) Radiation surveys and survey records.

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and used at each site where radiographic exposures are made.

b. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

c. All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 45.1(15), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that 45.1(15) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

d. Records shall be kept of the surveys required by 45.2(5) "b" and "c." Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.2(6) Special requirements and exemptions for enclosed radiography.

a. Systems for enclosed radiography, including shielded-room radiography and cabinet radiography, designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this chapter and 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of three years after the evaluation.

b. Certified and certifiable cabinet X-ray systems are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with individual monitoring devices in accordance with the appropriate provisions of 641—40.37(136C).

(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the agency until disposition is authorized by the agency.

(3) Tests for proper operation of interlocks used to control entry to the high radiation area or alarm systems, where applicable, shall be conducted and recorded every three months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to 641—38.3(136C).

45.2(7) Registration for industrial radiographic operations.

a. Radiation machines used in industrial radiographic operations shall be registered in accordance with 641—Chapter 39.

b. In addition to the registration requirements in 641—Chapter 39, an application for a certificate of registration shall include the following information:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,
2. Periodic training,
3. On-the-job training, and
4. Methods to be used by the registrant to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, registration requirements, and the operating and emergency procedures of the applicant.
 - (2) Written operating and emergency procedures, including all items listed in Appendix D.
 - (3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow registration provisions, rules of the agency, and the applicant's operating and emergency procedures.
 - (4) A list of permanent radiographic installations and descriptions of permanent storage and use locations.
 - (5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.
- c. A certificate of registration will be issued if the requirements of 641—Chapter 39 and this subrule are met.

641—45.3(136C) Radiation safety requirements for use of sealed sources of radiation in industrial radiography.

45.3(1) *Limits on external radiation levels from storage containers and source changers.* The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisievert) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

45.3(2) *Locking of sources of radiation.*

a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental removal of the sealed source. Either the exposure device or its container must be kept locked and, if applicable, the key removed, at all times when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 45.1(14). Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if the lock is a keyed lock, with the key removed at all times) when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to ensure that the sealed source is in the shielded position.

c. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 45.3(7) "b."

45.3(3) *Storage precautions.*

a. Labeling, storage, and transportation.

(1) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording: "CAUTION RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company)" or "DANGER RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company)."

(2) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 641—39.5(136C).

(3) Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

b. Radiographic exposure devices, source changers, or storage containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with 45.3(3) “*c.*,” and if the vehicle does not constitute a permanent storage location as described in 45.1(9).

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

- (1) Telephone service is established by the licensee;
- (2) Industrial radiographic services are advertised for or from the location;
- (3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

45.3(4) Performance requirements for radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432-1980, “Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography” (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036, telephone (212)642-4900.

b. In addition to the requirements specified in paragraph “*a.*” of this subrule, the following requirements apply to radiographic exposure devices, source changers, source assemblies, sealed sources, and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and the date on which this activity was last measured;
3. Model number (or product code) and serial number of the sealed source;
4. Manufacturer’s identity of the sealed source; and
5. Licensee’s name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 641—39.5(136C).

(3) Modification of any radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in paragraphs “*a.*” and “*b.*” of this subrule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or source changing:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter;

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with safe operation of the exposure device or associated equipment;

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

(6) Guide tubes must be used when moving the source out of the device;

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations;

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980;

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, must comply with the requirements of this subrule.

e. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this subrule.

f. Notwithstanding the requirements of 45.3(4) "a," equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

g. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component pursuant to the above-referenced standard.

45.3(5) *Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.*

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state.

b. Leak testing requirements.

(1) Each licensee that uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by this agency. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by this agency to perform the analysis.

(2) The licensee shall maintain records of the leak tests results for sealed sources and devices containing depleted uranium (DU). The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for

leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

c. Any test conducted under this subrule which reveals the presence of 0.005 microcuries (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw from use the equipment involved and shall have it decontaminated and repaired or disposed of in accordance with agency rules. Within five days after obtaining the results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.

d. Each exposure device using DU shielding and an “S” tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency to perform the analysis. Should such testing reveal the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU-shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination if the interval of storage exceeds 12 months.

e. Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: “Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found.”

45.3(6) *Operating and emergency procedures.*

a. The licensee’s operating and emergency procedures shall include instructions in at least the following:

- (1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 641—Chapter 40;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;
- (7) Minimizing exposure of individuals in the event of an accident;
- (8) The procedure for notifying proper personnel in the event of an accident;
- (9) Maintenance of records;
- (10) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, source changers, storage containers, and radiation machines;
- (11) The procedure(s) for identifying and reporting defects and noncompliance in 10 CFR Part 21; and
- (12) Source recovery procedure if the licensee will perform source recovery.

b. Rescinded IAB 4/8/98, effective 7/1/98.

c. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer’s assistant. If one of the personnel is a radiographer’s assistant, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography shall not be performed if only one qualified individual is present.

d. Collimators shall be used in industrial radiographic operations which use crank-out devices except when physically impossible.

e. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the agency.

45.3(7) Radiation surveys and survey records.

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and for each exposure device used at each site where radiographic exposures are made.

b. A survey with a calibrated and operable radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube and collimator. The survey required by this subrule must be done before exchanging films, repositioning the exposure head or dismantling the equipment.

c. (1) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 641—40.61(136C), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (i.e., with the sealed source in the exposed position) to confirm that 641—40.61(136C) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

(2) Each time the exposure device is relocated or the exposed position of the sealed source is changed, the requirements of 45.3(7)“c”(1) shall be met.

d. A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be made to determine that each sealed source is in its shielded position before securing the radiographic exposure device or source changer.

e. The sealed source shall be secured in its shielded position by locking the radiographic exposure device or source changer each time the sealed source is returned to its shielded position.

f. Each radiographic exposure device and source changer shall be locked and the key removed from any keyed lock prior to being moved or transported from one location to another and also prior to being stored at a given location.

g. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

h. Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 641—40.15(136C). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

i. A survey meeting the requirements of 45.3(7)“b” shall be performed on the radiographic exposure device and the source changer after every sealed source exchange. A survey shall be made of the storage area as defined in 641—45.2(136C) whenever a radiographic exposure device is being placed in storage.

j. Records shall be kept of the surveys required by 45.3(7)“c,” “d,” “g,” “h,” and “i.” Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual’s exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.3(8) Requirements for enclosed radiography.

a. Systems for enclosed radiography, including shielded-room radiography designed to allow admittance of individuals shall comply with all applicable requirements of this chapter.

b. Procedures shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with 45.1(9)“b.”

45.3(9) Underwater, offshore platform, and lay-barge radiography.

a. Underwater, offshore platform, or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 641—paragraph 39.4(27)“*e.*”

b. In addition to the other rules of this chapter, the following rules apply to the performance of lay-barge or offshore platform radiography:

(1) Cobalt-60 sources with activities in excess of 20 curies (nominal) and iridium-192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of lay-barge or offshore platform industrial radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay-barge or offshore platforms.

45.3(10) Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

45.3(11) Licensing for industrial radiographic operations. Rescinded IAB 4/5/00, effective 5/10/00. [ARC 1639C, IAB 10/1/14, effective 11/5/14; ARC 3746C, IAB 4/11/18, effective 5/16/18]

641—45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

45.4(1) Purpose and scope.

a. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C).

c. The requirements of 45.1(10)“*b*”(2) and (3) and 45.1(10)“*d*”(1)“2” do not apply to nonradiographic uses.

45.4(2) Definitions. For purposes of this subrule, definitions in 641—Chapters 38 and 40 and subrule 45.1(2) may also apply. As used in this rule, the following definitions apply:

“*Cold pasteurization*” means the process of using radiation for destroying disease-causing microorganisms in commercial products.

“*Self-shielded particle accelerator*” means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

“*Shielded facility*” means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40, or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

45.4(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C) and the following requirements:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

b. For accelerator facilities required to be licensed in accordance with 45.4(3), those operations that would require personnel monitoring, pursuant to 641—40.37(136C), due to the presence of radioactive material, shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance as well as routine operations.

45.4(4) *General requirements for the issuance of a registration or license for particle accelerators.* Along with the requirements of 641—39.1(136C) to 641—39.4(136C), an application for use of a particle accelerator will be approved only if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 45.4(4);

d. The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;

e. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has an adequate training program for operators of particle accelerators.

45.4(5) *Personnel monitoring.* In addition to the requirements of 641—Chapter 40, personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area; and

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

45.4(6) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed six months. If an operator has not participated in an accelerator operation for more than six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of 45.1(10).

45.4(7) *Shielding and safety design requirements.*

a. A qualified expert acceptable to the agency shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

c. In addition to the requirements of 45.4(8) "a" and "b," shielded facilities or self-shielded particle accelerators shall meet the following requirements:

(1) Authorization, by issuance of a construction permit, shall be granted upon a determination of adequacy being made pursuant to the review of an initial application of the shielding design, physical plant, and site specifications, and of the applicant's proposed equipment, uses and workloads. For a shielded facility, the applicant shall submit an evaluation of the shielding design by a qualified expert. For a self-shielded particle accelerator, the applicant need not submit an evaluation of a shielding design if an evaluation by an appropriate regulatory authority has been performed. The applicant may instead reference this evaluation. The applicant shall maintain a copy of the evaluation of shielding design for agency review.

(2) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made; and

(3) Operational use of an accelerator shall be authorized only after determination of adequacy of the items listed in 45.4(4) has been made by the agency.

45.4(8) Particle accelerator controls and interlock systems.

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible and located outside the high radiation area.

b. Each entrance into a target area or other high radiation area shall be provided with two safety interlocks that shut down the machine when the barrier is breached.

c. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

45.4(9) Warning devices.

a. Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Each high radiation area shall have an audible warning device that shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—40.61(136C).

45.4(10) Operating and emergency procedures.

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency for three years.

d. All incidents in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency for three years.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

- (1) Authorized by the radiation safety officer and, if applicable, the radiation safety committee;
- (2) Recorded in a permanent log and a notice posted at the accelerator control console; and
- (3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include the following:

- (1) Operation and safety instructions on the accelerator(s) to be used;
- (2) Methods for controlling access to restricted areas;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Use of personnel monitoring equipment;
- (5) The procedure for notifying proper personnel in the event of an accident;
- (6) Maintenance of records;
- (7) Inspections and maintenance of the accelerator; and
- (8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

45.4(11) Radiation monitoring requirements.

a. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

b. Accelerator facilities shall survey with a radiation detection instrument at intervals not to exceed 12 months. Records of this survey shall be maintained for agency review for three years.

c. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

d. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage. In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator. Records of this survey shall be maintained for agency review for three years.

e. Accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

f. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

g. Upon installation, all area monitoring equipment shall be tested to assure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

h. Whenever applicable, accelerator facilities registered or licensed pursuant to 45.4(3) "a" shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

i. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert who is acceptable to the agency.

j. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

45.4(12) Radiation safety officer.

a. Each registrant shall appoint a radiation safety officer that meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents two years of radiation protection experience.

b. The specific duties of the RSO include, but are not limited to, the following:

(1) To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

(2) To oversee and approve all phases of the training program for accelerator operators so that appropriate and effective radiation protection practices are taught;

- (3) To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;
- (4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;
- (5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;
- (6) To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;
- (7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
- (8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
- (9) To maintain records as required by these rules;
- (10) To ensure the proper storing, labeling, and use of the accelerator;
- (11) To ensure that inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.4(10)“c”; and
- (12) To ensure that personnel are complying with these rules and the operating and emergency procedures of the registrant.

641—45.5(136C) Radiation safety requirements for analytical X-ray equipment.

45.5(1) Purpose and scope. This rule provides special requirements for analytical X-ray equipment. The requirements of this rule are in addition to, and not in substitution for, 641—Chapters 38, 39, and 40. The requirements of rules 641—45.1(136C) to 641—45.4(136C) do not apply.

45.5(2) Definitions. For the purpose of this subrule, definitions in 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

“*Analytical X-ray equipment*” means equipment used for X-ray diffraction or fluorescence analysis.

“*Analytical X-ray system*” means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

“*Fail-safe characteristics*” means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

“*Local components*” means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

“*Normal operating procedures*” means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

“*Open-beam configuration*” means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

“*Primary beam*” means radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

45.5(3) Equipment requirements.

a. Safety device. A device which prevents the entry of any portion of an individual’s body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

- (1) A description of the various safety devices that have been evaluated;
- (2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

1. X-ray tube “on-off” status located near the radiation source housing, if the primary beam is controlled in this manner; or

2. Shutter “open-closed” status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) An easily visible warning light labeled with the words “X-RAY ON,” or words having a similar intent, shall be located:

1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these rules, warning devices shall have fail-safe characteristics.

c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) “CAUTION—HIGH INTENSITY X-RAY BEAM,” or words having a similar intent, on the X-ray source housing; and

(2) “CAUTION—RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

(3) “CAUTION—RADIOACTIVE MATERIAL,” or words having a similar intent, on the source housing in accordance with 641—40.63(136C) if the radiation source is a radionuclide.

e. Shutters. On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

(1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

45.5(4) Area requirements.

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 641—40.26(136C). For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys.

(1) Radiation surveys, as required by 641—40.36(136C), of all analytical X-ray systems sufficient to show compliance with 45.5(4) “a” shall be performed:

1. Upon installation of the equipment, and at least once every 12 months thereafter;

2. Following any change in the initial arrangement, number, or type of local components in the system;
3. Following any maintenance requiring the disassembly or removal of a local component in the system;
4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;
5. Anytime a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 641—40.15(136C).

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with 45.5(4) “a” to the satisfaction of the agency.

c. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words “CAUTION—X-RAY EQUIPMENT” or words having a similar intent in accordance with 641—subrule 40.61(1).

45.5(5) Operating requirements.

a. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words “SAFETY DEVICE NOT WORKING,” or words having a similar intent, shall be placed on the radiation source housing.

c. Repair or modification of X-ray tube systems. Except as specified in 45.5(5) “b,” no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.5(6) Personnel requirements.

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

- (1) Identification of radiation hazards associated with the use of the equipment;
- (2) Significance of the various radiation warnings, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
- (3) Proper operating procedures for the equipment;
- (4) Recognition of symptoms of an acute localized exposure; and
- (5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

- (1) Finger or wrist dosimetry devices shall be provided to and shall be used by:
 1. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 2. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 40.2(1) unless evaluated by a qualified expert.

641—45.6(136C) Radiation safety requirements for well-logging, wireline service operations and subsurface tracer studies.

45.6(1) Purpose. This rule establishes radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this rule are in addition to, and not in substitution for, the requirements of 641—Chapters 38, 39, and 40. The requirements of 641—45.1(136C) to 641—45.5(136C) do not apply.

45.6(2) Scope. This rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

45.6(3) Definitions. For the purpose of this subrule, the definitions of 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

“Energy compensation source (ECS)” means a small sealed source, with an activity not exceeding 3.7 MBq (100 microcuries), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool’s calibration when in use.

“Fresh water aquifer” means a geologic formation that is capable of yielding fresh water to a well or spring.

“Injection tool” means a device used for controlled subsurface injection of radioactive tracer material.

“Logging assistant” means any individual who, under the direct supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 45.6(22).

“Logging supervisor” means the individual who uses licensed material or provides direct supervision in the use of licensed material at a temporary job site and who is responsible to the licensee for ensuring compliance with the requirements of these rules and the conditions of the license.

“Logging tool” means a device used subsurface to perform well-logging.

“Personal supervision” means guidance and instruction by the logging supervisor who is physically present at the temporary job site, who is in personal contact with logging assistants, and who can give immediate assistance.

“Radioactive marker” means licensed material used for depth determination or direction orientation. For purposes of this rule, this term includes radioactive collar markers and radioactive iron nails.

“Safety review” means a periodic review on radiation safety aspects of well-logging provided by the licensee for its employees. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

“Source holder” means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well-logging operations.

“Subsurface tracer study” means the release of unsealed licensed material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

“Surface casing” for protecting fresh water aquifers means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

“Temporary job site” means a place where licensed materials are present for the purpose of performing well-logging or subsurface tracer studies.

“Tritium neutron generator target source” means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

“Uranium sinker bar” means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

“Well” means a drilled hole in which well-logging may be performed. As used in this rule, “well” includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

“*Well-logging*” means all operations involving the lowering and raising of measuring devices or tools which may contain licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations and which may be used in oil, gas, mineral, groundwater, or geological exploration.

“*Wireline*” means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

“*Wireline service operation*” means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

45.6(4) Agreement with well owner or operator.

a. A licensee may perform well-logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

- (1) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;
- (2) A person may not attempt to recover a sealed source in a manner which, in the licensee’s opinion, could result in its rupture;
- (3) The radiation monitoring required in 45.6(8) and 45.6(17) will be performed;
- (4) If the environment, any equipment, or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and
- (5) If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

1. Each irretrievable well-logging source must be immobilized and sealed in place with a cement plug;

2. There must be a means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

3. A permanent identification plaque, constructed of long-lasting material, such as stainless steel, brass, bronze, or Monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 17 cm (7 inches) square and 3 mm (1/8-inch) thick.

The plaque must contain:

- The word “Caution”;
- The radiation symbol (the color requirement in 641—40.60(136C) need not be met);
- The date the source was abandoned;
- The name of the well owner or well operator, as appropriate;
- The well name and well identification number(s) or other designation;
- An identification of the sealed source(s) by radionuclide and quantity;
- The depth of the source and depth to the top of the plug; and
- An appropriate warning such as, “Do not reenter this well.”

b. The licensee shall retain a copy of the written agreement for three years after the completion of the well-logging operation.

c. A licensee may apply, pursuant to 641—38.3(136C), for agency approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well-logging source in a manner not otherwise authorized in 45.6(26) “a”(5).

d. A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in 45.6(26) “a”(1) through (5).

45.6(5) Limits on levels of radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 641—39.5(136C) and the dose limitation requirements of 641—Chapter 40 are met.

45.6(6) Storage precautions.

a. Each source of radiation shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

45.6(7) Transport precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

45.6(8) Radiation survey instruments.

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this subrule and by 641—40.36(136C). Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour.

b. Each radiation survey instrument shall be calibrated:

- (1) At intervals not to exceed six months and after each instrument servicing;
- (2) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and
- (3) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

c. Calibration records shall be maintained for a period of two years for inspection by the agency.

45.6(9) Leak testing of sealed sources.

a. *Testing and record-keeping requirements.* Each licensee using sealed sources of radioactive material shall have the sources tested for leakage periodically. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for three years after the leak test is performed.

b. *Method of testing.* Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the NRC, an agreement state, or a licensing state. The wipe of a sealed source must be performed using a leak test kit or method approved by the NRC, an agreement state, or a licensing state. The wipe sample must be taken from the nearest assessable point to the sealed source where contamination might accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

c. *Interval of testing.*

(1) Each sealed source of radioactive material (except an energy compensation source (ECS)) shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made six months prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(2) Each ECS that is not exempt from testing in accordance with 45.6(9)“c”(1) must be tested at intervals not to exceed three years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the ECS may not be used until tested.

d. *Leaking or contaminated sources.*

(1) If the test in 45.6(9)“c” reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of by an NRC, agreement state, or licensing state licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by an NRC, agreement state, or licensing state licensee that is authorized to perform these functions.

(2) A report describing the equipment involved, the test results, any contamination which resulted from the leaking source, and the corrective action taken up to the time of the report shall be filed with the agency within five days of receiving the test results.

e. *Exemptions.* The following sources are exempted from the periodic leak test requirements of 45.6(9)“a” to “d”:

- (1) Hydrogen-3 (tritium) sources;
- (2) Sources of radioactive material with a half-life of 30 days or less;
- (3) Sealed sources of radioactive material in gaseous form;

(4) Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) Sources of alpha- or neutron-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

45.6(10) Quarterly inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

45.6(11) Utilization records. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:

- a. Make, model number, and a serial number or a description of each source of radiation used;
- b. The identity of the well-logging supervisor or field unit to whom assigned;
- c. Locations where used and dates of use; and
- d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

45.6(12) Design, performance, and certification criteria for sealed sources used in well-logging operations.

- a. A licensee may use a sealed source for use in well-logging applications if:
 - (1) The sealed source is doubly encapsulated construction;
 - (2) The sealed source contains chemical and physical forms that are as insoluble and nondispersible as practical; and
 - (3) The sealed source meets the requirements of 45.6(12) "b," "c," and "d."
- b. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source for use in well-logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in 45.6(12) "c" or "d."
- c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for well-logging applications if it meets the oil-well-logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources—Classification."
- d. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source for use in well-logging applications if the sealed source's prototype has been tested and found to maintain its integrity after each of the following tests.
 - (1) Temperature. The test source must be held at -40 degrees C for 20 minutes, 600 degrees C for one hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees C within 15 seconds.
 - (2) Impact test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.
 - (3) Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes.
 - (4) Puncture test. A one gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.
 - (5) Pressure test. The test source must be subject to an external pressure of 1.695×10^7 pascals (24,600 pounds per square inch absolute).
- e. The requirements in 45.6(12) "a," "b," "c," and "d" do not apply to sealed sources that contain licensed material in gaseous form.
- f. The requirements of 45.6(12) "a," "b," "c," and "d" do not apply to energy compensation sources (ECS). ECSs must be registered with the NRC, licensing state, or agreement state.

45.6(13) Labeling.

- a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER¹
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER¹
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES
[OR NAME OF COMPANY]

45.6(14) *Inspection and maintenance.*

a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to ensure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

b. If any inspection conducted pursuant to 45.6(14) “*a*” reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

c. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform this operation.

d. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.6(15) *Training requirements.*

a. No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this rule until such individual has:

(1) Received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Appendix E of this chapter and demonstrated an understanding thereof;

(2) Read and received instruction in the rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee’s or registrant’s operating and emergency procedures, and demonstrated an understanding thereof; and

(3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

b. No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) Read or received instruction in the licensee’s or registrant’s operating and emergency procedures and demonstrated an understanding thereof; and

(2) Demonstrated competence to use, under the direct supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

c. The licensee or registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual’s employment.

45.6(16) *Operating and emergency procedures.* Each licensee or registrant shall develop and follow written operating and emergency procedures that cover:

a. The handling and use of sources of radiation, including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

b. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

c. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 45.6(22);

- d. Minimizing personnel exposure, including exposures from inhalation and ingestion of licensed tracer materials;
- e. Methods and occasions for locking and securing stored licensed or registered materials;
- f. Personnel monitoring and the use of personnel monitoring equipment;
- g. Transportation of licensed or registered materials to field stations or temporary job sites, packaging of licensed or registered materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;
- h. Picking up, receiving, and opening packages containing licensed or registered materials, in accordance with 641—40.65(136C);
- i. For the use of tracers, decontamination of the environment, equipment, and personnel;
- j. Maintenance of records generated by well logging personnel at temporary job sites;
- k. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 45.6(14);
- l. Identifying and reporting defects and noncompliance;
- m. Actions to be taken if a sealed source is lodged in a well;
- n. Notifying proper persons in the event of an accident; and
- o. Actions to be taken if a sealed source is ruptured that include actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required in 45.6(8).

45.6(17) Personnel monitoring.

a. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears, at all times during the handling of licensed radioactive materials, a film badge, OSL device or thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). Each film badge, OSL device or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSL devices and TLDs replaced at least quarterly. After replacement, each film badge, OSL device or TLD must be promptly processed.

b. The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

c. Personnel monitoring records and bioassay results shall be maintained for inspection until the agency authorizes disposition.

45.6(18) Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 641—Chapter 38.

45.6(19) Handling tools. The licensee shall provide and require the use of tools that will ensure remote handling of sealed sources other than low activity calibration sources.

45.6(20) Subsurface tracer studies.

a. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

b. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency and any other appropriate state agency.

45.6(21) Particle accelerators. No licensee or registrant shall permit aboveground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of 641—40.15(136C) and 641—40.26(136C), as applicable, are met.

45.6(22) Radiation surveys.

a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

b. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

c. If the sealed source assembly is removed from the logging tool before departing the job site, the logging tool detector shall be energized, or a survey meter used, to ensure that the logging tool is free of contamination.

d. Radiation surveys shall be made and recorded at the job site or wellhead for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

e. Records required pursuant to 45.6(22)“a” to “d” shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.

45.6(23) Documents and records required at field stations. Each licensee or registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:

- a. Appropriate license, certificate of registration, or equivalent document(s);
- b. Operating and emergency procedures;
- c. Applicable regulations;
- d. Records of the latest survey instrument calibrations pursuant to 45.6(8);
- e. Records of the latest leak test results pursuant to 45.6(9);
- f. Records of quarterly inventories required pursuant to 45.6(10);
- g. Utilization records required pursuant to 45.6(11);
- h. Records of inspection and maintenance required pursuant to 45.6(14);
- i. Survey records required pursuant to 45.6(22); and
- j. Training records required pursuant to 45.6(15).

45.6(24) Documents and records required at temporary job sites. Each licensee or registrant conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by the agency:

- a. Operating and emergency procedures;
- b. Survey records required pursuant to 45.6(22) for the period of operation at the site;
- c. Evidence of current calibration for the radiation survey instruments in use at the site;
- d. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and
- e. Shipping papers for the transportation of radioactive material.

45.6(25) Notification of incidents, abandonment, and lost sources.

a. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 641—Chapter 40.

b. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(2) Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

c. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) Advise the well operator of the regulations of the appropriate state agency regarding abandonment and an appropriate method of abandonment, which shall include:

1. The immobilization and sealing in place of the radioactive source with a cement plug;

2. The setting of a whipstock or other deflection device; and
 3. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by 45.6(25) "d."

(2) Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures, or specify the implemented abandonment before receiving approval because the licensee believed there was an immediate threat to public health and safety; and

(3) File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the appropriate state agency that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

1. Date of occurrence;
2. A description of the well-logging source involved, including the radionuclide and its quantity, chemical, and physical form;
3. Surface location and identification of the well;
4. Results of efforts to immobilize and seal the source in place;
5. A brief description of the attempted recovery effort;
6. Depth of the source;
7. Depth of the top of the cement plug;
8. Depth of the well;
9. The immediate threat to public health and safety justification for implementing abandonment if prior approval was not obtained in accordance with 45.6(25) "c"(2);
10. Any other information, such as a warning statement, contained on the permanent identification plaque; and
11. The names of state agencies receiving a copy of this report.

d. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque² for posting the well or well-bore. This plaque shall:

- (1) Be constructed of long-lasting material, such as stainless steel or Monel; and
- (2) Contain the following information engraved on its face:

1. The word "CAUTION";
2. The radiation symbol without the conventional color requirement;
3. The date of abandonment;
4. The name of the well operator or well owner;
5. The well name and well identification number(s) or other designation;
6. The sealed source(s) by radionuclide and activity;
7. The source depth and the depth to the top of the plug; and
8. An appropriate warning, depending on the specific circumstances of each abandonment.³

e. The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

45.6(26) Reserved.

45.6(27) *Radioactive markers.* The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the quantities specified in 641—Chapter 39, Appendix B, Exempt Quantities. The use of markers is subject only to the requirements of 45.6(10).

45.6(28) *Uranium sinker bars.* The licensee may use uranium sinker bars in well-logging applications only if they are legibly impressed with the words "CAUTION—RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES [or Company name] IF FOUND."

45.6(29) *Use of a sealed source in a well without a surface casing.* The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a

procedure for reducing the probability of the source's becoming lodged in the well. The procedure must be approved by the NRC or licensing or agreement state.

45.6(30) *Energy compensation source.* The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

a. For well-logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(9) to 45.6(11).

b. For well-logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 45.6(4), 45.6(9) to 45.6(11), 45.6(25), and 45.6(29).

45.6(31) *Tritium neutron generator target source.*

a. Use of a tritium neutron generator target source that contains quantities not exceeding 30 curies (1110 MBq) and that is in a well with a surface casing to protect fresh water aquifers is subject to the requirements of this rule except subrules 45.6(4), 45.6(12), and 45.6(25).

b. Use of a tritium neutron generator target source that contains quantities exceeding 30 curies (1110 MBq) or that is in a well without a surface casing to protect fresh water aquifers is subject to the requirements of this rule except subrule 45.6(12).

¹or CAUTION

²An example of a suggested plaque is shown in Appendix F of this chapter.

³Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Iowa Department of Public Health."

CHAPTER 45—APPENDIX A

SUBJECTS FOR INSTRUCTION OF
RADIOGRAPHER'S ASSISTANTS

Training provided to qualify individuals as radiographer's assistants in compliance with 45.1(10) shall be presented on a formal basis. The training shall include the following subjects:

- I. Fundamentals of radiation safety
 - A. Characteristics of radiation
 - B. Units of radiation dose and quantity of radioactivity
 - C. Significance of radiation dose
 1. Radiation protection standards
 2. Biological effects of radiation
 3. Case histories of radiography accidents
 - D. Levels of radiation from sources of radiation
 - E. Methods of controlling radiation dose
 1. Working time
 2. Working distances
 3. Shielding
- II. Radiation detection instrumentation to be used
 - A. Use of radiation survey instruments
 1. Operation
 2. Calibration
 3. Limitations
 - B. Survey techniques
 - C. Use of personnel monitoring equipment
 1. Film badges
 2. Thermoluminescent dosimeters (TLDs)
 3. Pocket dosimeters
 4. OSL devices
- III. The requirements of pertinent federal and state regulations
- IV. The licensee's or registrant's written operating and emergency procedures
- V. Radiographic equipment to be used
 - A. Remote handling equipment
 - B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed)
 - C. Storage and transport containers, source changers
 - D. Operation and control of X-ray equipment
 - E. Collimators

CHAPTER 45—APPENDIX B

GENERAL REQUIREMENTS FOR INSPECTION OF
INDUSTRIAL RADIOGRAPHIC EQUIPMENT

- I. Panoramic devices (devices in which the sealed source is physically removed from the shielded container during exposure) shall be inspected for:
 - A. Radiographic exposure unit
 - 1. Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;
 - 2. Condition of safety plugs;
 - 3. Proper operation of locking mechanism;
 - 4. Condition of pigtail connector;
 - 5. Condition of carrying device (straps, handle, etc.);
 - 6. Proper labeling.
 - B. Source tube
 - 1. Rust, dirt, or sludge buildup inside the source tube;
 - 2. Condition of source tube connector;
 - 3. Condition of source stop;
 - 4. Kinks or damage that could prevent proper operation;
 - 5. Presence of radioactive contamination.
 - C. Control cables and drive mechanism
 - 1. Proper drive mechanism with camera, as appropriate;
 - 2. Changes in general operating characteristics;
 - 3. Condition of connector on drive cable;
 - 4. Drive cable flexibility, wear, and rust;
 - 5. Excessive wear or damage to crank assembly parts;
 - 6. Damage to drive cable conduit that could prevent the cable from moving easily;
 - 7. Connection of the control cable connector with the pigtail connector for proper mating;
 - 8. Proper operation of source position indicator, if applicable;
 - 9. Presence of radioactive contamination.
- II. Directional beam devices shall be inspected for:
 - A. Abnormal surface radiation;
 - B. Changes in the general operating characteristics of the unit;
 - C. Proper operation of shutter mechanism;
 - D. Chafing or binding of shutter mechanism;
 - E. Damage to the device that might impair its operation;
 - F. Proper operation of locking mechanism;
 - G. Proper drive mechanism with camera, as appropriate;
 - H. Condition of carrying device (strap, handle, etc.);
 - I. Proper labeling.
- III. X-ray equipment shall be inspected for:
 - A. Change in the general operating characteristics of the unit;
 - B. Wear of electrical cables and connectors;
 - C. Proper labeling of console;
 - D. Proper console with machine, as appropriate;
 - E. Proper operation of locking mechanism;
 - F. Timer run-down cutoff;
 - G. Damage to tube head housing that might result in excessive radiation levels.

CHAPTER 45—APPENDIX C

TIME REQUIREMENTS FOR RECORD KEEPING

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(4)	Receipt, transfer and disposal.	3 years.
45.1(5)	Survey instrument calibrations.	3 years.
45.1(6)	Quarterly inventory.	3 years.
45.1(7)	Utilization logs.	3 years.
45.1(8)	Quarterly inspection and maintenance.	3 years.
45.1(9)	High radiation area control devices or alarm systems.	Until disposal is authorized by the agency.
45.1(10)	Training and testing records.	3 years.
45.1(12)	Pocket dosimeter readings.	3 years.
	Pocket dosimeter calibrations.	3 years.
	Film badge, OSL device, or TLD reports.	Until the agency terminates the license.
	Alarming ratemeter calibrations.	3 years.
	Alarming ratemeter functions.	3 years.
	Estimates of overexposures.	Until the agency terminates the license.
45.1(19)	Current operating and emergency procedures.	Until the license is terminated.
	Superseded material.	3 years after change.
40.81(1)	Internal audit program.	3 years.
45.1(11)	Radiographer audits.	3 years.
45.2(5) and 45.3(7)	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure.
45.1(16)	Records at temporary job sites.	During temporary job site operations.
45.2(6) and 45.3(8)	Annual evaluation of enclosed X-ray systems.	2 years.
45.3(5)	Leak tests.	3 years.
45.2(6)	Evaluation of certified cabinet X-ray systems.	2 years.

CHAPTER 45—APPENDIX D

OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

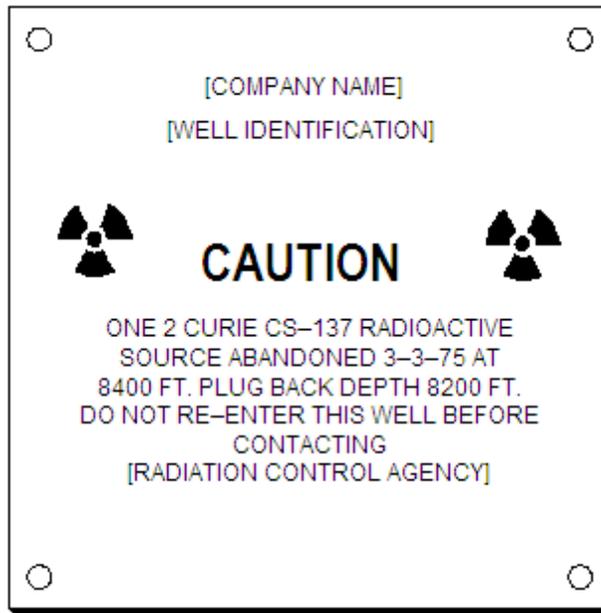
- A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in 641—Chapter 40;
- B. Methods and occasions for conducting radiation surveys, including lock-out survey requirements;
- C. Methods for controlling access to industrial radiography areas;
- D. Methods and occasions for locking and securing sources or radiation;
- E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off-scale;
- F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable U.S. Department of Transportation requirements);
- G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;
- H. Procedures for notifying proper personnel in the event of an accident;
- I. Specific posting requirements;
- J. Maintenance of records (Appendix C); and
- K. Inspection and maintenance of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines.

CHAPTER 45—APPENDIX E

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

- I. Fundamentals of radiation safety.
 - A. Characteristics of radiation.
 - B. Units of radiation dose and quantity of radioactivity.
 - C. Significance of radiation dose.
 - 1. Radiation protection standards.
 - 2. Biological effects of radiation dose.
 - D. Levels of radiation from sources of radiation.
 - E. Methods of minimizing radiation dose.
 - 1. Working time.
 - 2. Working distances.
 - 3. Shielding.
 - F. Radiation safety practices including prevention of contamination and methods of decontamination.
- II. Radiation detection instrumentation to be used.
 - A. Use of radiation survey instruments.
 - 1. Operation.
 - 2. Calibration.
 - 3. Limitations.
 - B. Survey techniques.
 - C. Use of personnel monitoring equipment.
- III. Equipment to be used.
 - A. Handling equipment.
 - B. Sources of radiation.
 - C. Storage and control of equipment.
 - D. Operation and control of equipment.
- IV. The requirements of pertinent federal and state regulations.
 - V. The licensee's or registrant's written operating and emergency procedures.
- VI. The licensee's or registrant's record-keeping procedures.

CHAPTER 45—APPENDIX F

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES
CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word “CAUTION” should be approximately twice the letter size of the rest of the information, e.g., ½-inch and ¼-inch letter size, respectively.

These rules are intended to implement Iowa Code chapters 136B and 136C.

- [Filed 4/7/80, Notice 2/6/80—published 4/30/80, effective 7/1/80]
- [Filed 5/17/85, Notice 2/27/85—published 6/5/85, effective, see rule 41.7]
- [Filed 11/6/87, Notice 9/23/87—published 12/2/87, effective 1/6/88]
- [Filed 7/17/92, Notice 5/27/92—published 8/5/92, effective 9/9/92]
- [Filed 9/17/93, Notice 8/4/93—published 10/13/93, effective 1/1/94]
- [Filed 7/14/94, Notice 6/8/94—published 8/3/94, effective 9/7/94]
- [Filed 5/15/95, Notice 3/29/95—published 6/7/95, effective 7/12/95]
- [Filed 1/11/96, Notice 10/11/95—published 1/31/96, effective 3/6/96]
- [Filed 9/16/96, Notice 7/17/96—published 10/9/96, effective 11/16/96]
- [Filed 5/16/97, Notice 4/9/97—published 6/4/97, effective 7/9/97]
- [Filed 3/18/98, Notice 1/14/98—published 4/8/98, effective 7/1/98]
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- [Filed 6/25/99, Notice 5/5/99—published 7/14/99, effective 9/15/99]
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- [Filed 11/15/02, Notice 10/2/02—published 12/11/02, effective 1/15/03]
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- [Filed 3/12/04, Notice 2/4/04—published 3/31/04, effective 5/5/04]
- [Filed 3/11/05, Notice 2/2/05—published 3/30/05, effective 5/4/05]
- [Filed 3/9/06, Notice 2/1/06—published 3/29/06, effective 5/3/06]
- [Filed 7/13/07, Notice 6/6/07—published 8/1/07, effective 9/5/07]

[Filed ARC 8982B (Notice ARC 8762B, IAB 5/19/10), IAB 8/11/10, effective 9/15/10]
[Filed ARC 1639C (Notice ARC 1470C, IAB 5/28/14), IAB 10/1/14, effective 11/5/14]
[Filed ARC 3746C (Notice ARC 3578C, IAB 1/17/18), IAB 4/11/18, effective 5/16/18]
[Filed ARC 5059C (Notice ARC 4856C, IAB 1/15/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 55
ADVISORY COUNCIL ON BRAIN INJURIES
[Prior to 9/30/92, see Persons with Disabilities Division[431] Ch 3]

641—55.1(135) Definitions. For the purposes of this chapter, the following definitions shall apply:

“*Appointed members*” means members of the advisory council on brain injuries who have been appointed by the governor’s office.

“*Brain injury*” means a brain injury as defined in Iowa Code section 135.22.

“*Chairperson*” means the chairperson of the advisory council on brain injuries, who has been elected by the majority of the council’s members.

“*Council*” means the advisory council on brain injuries.

“*Department*” means the Iowa department of public health.

“*Ex officio members*” means designated state agency staff who are statutory members of the advisory council on brain injuries.

“*Person from the public*” means a person or agency who does not have an affiliation with the advisory council on brain injuries but who has knowledge or skills beneficial to the council for specific task forces or projects.

“*Service partners*” means representatives of organizations who partner with the Iowa department of public health or the advisory council on brain injuries to carry out activities related to the mission of the council.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.2(135) Mission of council. The council’s mission is to represent individuals with brain injury, their families, and all Iowans through advocacy, education, training, rehabilitation, research and prevention. By means of these efforts, the council brings about awareness to others and serves as a source of hope and healing to survivors of brain injury. The council will accomplish this mission through the following activities:

1. Studying the needs of individuals with brain injury and their families.
2. Making recommendations regarding the planning, development, and administration of a comprehensive statewide service delivery system.
3. Promoting and implementing injury prevention strategies.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.3(135) Council established. The advisory council on brain injuries, part of the Iowa department of public health, is established pursuant to Iowa Code section 135.22A.

55.3(1) The council shall consist of a minimum of nine appointed members in addition to the ex officio members.

a. The following persons or their designees shall serve as ex officio, nonvoting members of the council:

- (1) The director of public health.
 - (2) The director of human services and any division administrators of the department of human services so assigned by the director.
 - (3) The director of the department of education.
 - (4) The chief of the special education bureau of the department of education.
 - (5) The administrator of the division of vocational rehabilitation services of the department of education.
 - (6) The director of the department for the blind.
 - (7) The commissioner of insurance.
- b.* Appointed members.

(1) Insofar as practicable, the council shall include persons with brain injuries; family members of persons with brain injuries; representatives of industry, labor, business, and agriculture; representatives of federal, state, and local government; and representatives of religious, charitable, fraternal, civic, educational, medical, legal, veteran, welfare, and other professional groups and organizations.

(2) Members shall be appointed to represent every geographic area of the state and shall include members of both sexes.

55.3(2) Appointed members' terms shall be for two years.

55.3(3) Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

55.3(4) Members whose terms expire may be reappointed.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.4(135) Officers.

55.4(1) Officers of the council shall be a chairperson, vice-chairperson and immediate past chairperson.

a. The officers shall be elected at the first meeting of each fiscal year.

b. Vacancy in the office of chairperson shall be filled by elevation of the vice-chairperson.

c. Vacancy in the office of vice-chairperson shall be filled by election at the next meeting after the vacancy occurs.

55.4(2) Duties of the officers.

a. The chairperson shall:

(1) Preside at all meetings of the council,

(2) Appoint such task forces as deemed necessary, and

(3) Designate the chairperson of each task force from the appointed members of the council.

b. The vice-chairperson shall:

(1) Perform the duties of the chairperson if the chairperson is absent or unable to act. When so acting, the vice-chairperson shall have all the powers of and be subject to all restrictions upon the chairperson.

(2) Perform such other duties as may be assigned by the chairperson.

c. The immediate past chairperson shall:

(1) Assist the chairperson at the first meeting of the chairperson's appointment.

(2) Perform the duties of the chairperson if the chairperson and vice-chairperson are absent or unable to act. When so acting, the immediate past chairperson shall have all the powers of and be subject to all restrictions upon the chairperson.

(3) Assist with note taking if there is no council staff person available.

(4) Assist the chairperson to identify council business and necessary task force meetings.

55.4(3) The officers shall serve until their successors are appointed.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.5(135) Duties of the council. The council shall perform the following duties:

55.5(1) Promote meetings and programs for the discussion of methods to reduce the debilitating effects of brain injuries, and disseminate information in cooperation with any other department, agency, or entity on the prevention, evaluation, care, treatment, and rehabilitation of persons affected by brain injuries.

55.5(2) Study and review current prevention, evaluation, care, treatment, and rehabilitation technologies and recommend appropriate preparation, training, retraining, and distribution of personnel and resources in the provision of services to persons with brain injuries through private and public residential facilities, day programs, and other specialized services.

55.5(3) Participate in developing and disseminating criteria and standards which may be required for future funding or licensing of facilities, day programs, and other specialized services for persons with brain injuries in Iowa.

55.5(4) Make recommendations to the governor for developing and administering a state plan to provide services for persons with brain injuries in Iowa.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.6(135) Meetings.

55.6(1) The council shall meet at least quarterly. The annual meeting schedule shall be established by the beginning of the fiscal year.

55.6(2) Notice of routine meetings and agenda will be made available to the members a minimum of five working days prior to the meeting.

55.6(3) Meetings may be scheduled as business requires, but notice must be given to members at least five working days prior to the meeting.

55.6(4) All meetings will be held in facilities accessible to and functional for people with physical disabilities.

55.6(5) Notification for reasonable accommodations should be made to department staff at least three working days prior to the meeting.

55.6(6) All meetings are open to the public in accordance with the open meetings law, Iowa Code chapter 21.

55.6(7) Cameras and recording devices may be used at open meetings, provided they do not obstruct the meeting. The presiding officer may request a person using such a device to discontinue its use if it is obstructing the meeting.

55.6(8) The presiding officer may exclude any person from the meeting for repeated behavior that disrupts or obstructs the meeting.

55.6(9) The operation of council meetings will be governed by the following rules of procedure:

a. A simple majority of the appointed members shall constitute a quorum. Motions may not be made without a quorum.

b. When a quorum is present, a motion is carried by affirmative vote of two-thirds of appointed members present.

c. Time for public comment will be made during each council meeting.

55.6(10) Meeting attendance.

a. Council members are expected to attend council meetings with the exception of extenuating circumstances that have been cleared beforehand by the chairperson.

b. Any council member who is unable to attend a meeting will notify council staff at least 24 hours prior to the start of a regularly scheduled meeting. A meeting may be canceled if attendance is expected to be low.

c. A teleconference option shall be set up for the members to participate in the meeting.

d. Appointed members may be recommended for dismissal from the council if they miss more than three meetings annually.

55.6(11) Special meetings. Special meetings shall be for business of the council that cannot wait until the next scheduled meeting.

a. Special meetings may be called by the chairperson to discuss emergent issues within a 24-hour time period.

b. A majority of council members may call a special meeting.

c. Special meetings shall be held in accordance with Iowa Code chapter 21.

55.6(12) Rescinded IAB 6/17/20, effective 7/22/20.

[ARC 9772B, IAB 10/5/11, effective 11/9/11; ARC 5060C, IAB 6/17/20, effective 7/22/20]

641—55.7(135) Minutes. The advisory council shall keep minutes of all its meetings showing the date, time, place, members present, members absent, and the general topics discussed.

55.7(1) The minutes shall reflect the actions agreed upon by the members for topics requiring the members' input or consensus.

55.7(2) If a meeting is convened within a 24-hour time period to discuss emergent issues, the minutes shall reflect the emergent nature of the meeting.

55.7(3) If a meeting is conducted via telephone, the minutes shall reflect the reason for the use of this method of meeting.

55.7(4) The minutes shall be available at the council staff office for inspection Monday through Friday from 8:30 a.m. to 4:30 p.m.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.8(135) Task forces. The chairperson of the council may establish task forces as needed to carry out the business of the council.

55.8(1) The council will have two standing task forces: the executive task force and the state plan task force.

a. The executive task force shall be made up of the council chairperson, vice-chairperson, immediate past chairperson and chairperson of the state plan task force.

b. The state plan task force shall be made up of members appointed by the chairperson.

55.8(2) The council may designate additional task forces to perform such duties as may be deemed necessary.

55.8(3) Task forces may be composed of appointed members, ex officio members, service partners, and persons from the public.

55.8(4) The chairperson of each task force will be an appointed member of the council.

55.8(5) All members of task forces shall have voting privileges during task force meetings; however, all decisions made by task forces must be approved at the next regular council meeting by a vote of the appointed members.

55.8(6) Task force meetings shall be scheduled at least five working days prior to the meeting.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

641—55.9(135) Expenses of advisory council members. The following may be considered necessary expenses for reimbursement of advisory council members when the expenses are incurred on behalf of advisory council business and are subject to established state reimbursement rates:

1. Reimbursement for travel in a private car.
2. Actual lodging and meal expenses, including sales tax on lodging and meals.
3. Actual expenses of public transportation.

[ARC 9772B, IAB 10/5/11, effective 11/9/11]

These rules are intended to implement Iowa Code section 135.22A.

[Filed 5/17/91, Notice 4/3/91—published 6/12/91, effective 7/17/91]

[Filed emergency 9/14/92—published 9/30/92, effective 9/14/92]

[Filed ARC 9772B (Notice ARC 9631B, IAB 7/27/11), IAB 10/5/11, effective 11/9/11]

[Filed ARC 5060C (Notice ARC 4999C, IAB 3/25/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 196
MILITARY SERVICE, VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE
MEMBERS

641—196.1(272C) Definitions.

“Department” means the department of public health.

“License” means a license, certification, registration, permit, approval, renewal, or other similar authorization issued to a person by a licensing authority which evidences the granting of authority to engage in a profession, occupation, or business.

“Licensing authority” means a board, commission, or any other entity of the department which has authority within this state to suspend or revoke a license or deny the renewal or issuance of a license authorizing a person to engage in a business, occupation, or profession.

“Military service” means honorably serving on federal active duty, state active duty, or national guard duty, as defined in Iowa Code section 29A.1; in the military services of other states, as provided in 10 U.S.C. Section 101(c); or in the organized reserves of the United States, as provided in 10 U.S.C. Section 10101.

“Military service applicant” means an individual requesting credit toward licensure for military education, training, or service obtained or completed in military service.

“Spouse” means a spouse of an active duty member of the military forces of the United States.

“Veteran” means an individual who meets the definition of “veteran” in Iowa Code section 35.1(2). [ARC 1749C, IAB 12/10/14, effective 1/14/15; ARC 5061C, IAB 6/17/20, effective 7/22/20]

641—196.2(272C) Military education, training, and service credit. A military service applicant may apply for credit for verified military education, training, or service toward any experience or educational requirement for licensure by submitting a military service application form to the licensing authority.

196.2(1) The application may be submitted with an application for licensure or examination, or prior to applying for licensure or to take an examination. No fee is required with submission of an application for military service credit.

196.2(2) The applicant shall identify the experience or educational licensure requirement to which the credit would be applied if granted. Credit shall not be applied to an examination requirement.

196.2(3) The applicant shall provide documents, military transcripts, a certified affidavit, or forms that verify completion of the relevant military education, training, or service, which may include, when applicable, the applicant’s Certificate of Release or Discharge from Active Duty (DD Form 214) or Verification of Military Experience and Training (VMET) (DD Form 2586).

196.2(4) Upon receipt of a completed military service application, the licensing authority shall promptly determine whether the verified military education, training, or service will satisfy all or any part of the identified experience or educational qualifications for licensure.

196.2(5) The licensing authority shall grant credit requested in the application in whole or in part if the licensing authority determines that the verified military education, training, or service satisfies all or part of the experience or educational qualifications for licensure.

196.2(6) The licensing authority shall inform the military service applicant in writing of the credit, if any, given toward an experience or educational qualification for licensure or explain why no credit was granted. The applicant may request reconsideration upon submission of additional documentation or information.

196.2(7) A military service applicant who is aggrieved by the licensing authority’s decision may request a contested case (administrative hearing) and may participate in a contested case by telephone. A request for a contested case shall be made within 30 days of issuance of the licensing authority’s decision. The provisions of 641—Chapter 173 shall apply, except that no fees or costs shall be assessed against the military service applicant in connection with a contested case conducted pursuant to this subrule.

196.2(8) The licensing authority shall grant or deny the military service application prior to ruling on the application for licensure. The applicant shall not be required to submit any fees in connection

with the licensure application unless the licensing authority grants the military service application. If the licensing authority does not grant the military service application, the applicant may withdraw the licensure application or request that the licensure application be placed in pending status for up to one year or as mutually agreed. The withdrawal of a licensure application shall not preclude subsequent applications supported by additional documentation or information.

[ARC 1749C, IAB 12/10/14, effective 1/14/15; ARC 5061C, IAB 6/17/20, effective 7/22/20]

641—196.3(272C) Veteran and active duty military spouse reciprocity.

196.3(1) A veteran or spouse with an unrestricted license in another jurisdiction may apply for licensure in Iowa through reciprocity. A veteran or spouse must pass any examinations required for licensure to be eligible for licensure through reciprocity and will be given credit for examinations previously passed when consistent with the licensing authority's laws and rules on examination requirements. A fully completed application for licensure submitted by a veteran or spouse under this subrule shall be given priority and shall be expedited.

196.3(2) Such an application shall contain all of the information required of all applicants for licensure who hold unrestricted licenses in other jurisdictions and who are applying for licensure by reciprocity, including, but not limited to, completion of all required forms, payment of applicable fees, disclosure of criminal or disciplinary history, and, if applicable, a criminal history background check. The applicant shall use the same forms as any other applicant for licensure by reciprocity and shall additionally provide such documentation as is reasonably needed to verify the applicant's status as a veteran under Iowa Code section 35.1(2) or a spouse of an active duty member of the military forces of the United States.

196.3(3) Upon receipt of a fully completed licensure application, the licensing authority shall promptly determine if the professional or occupational licensing requirements of the jurisdiction where the veteran or spouse is licensed are substantially equivalent to the licensing requirements in Iowa. The licensing authority shall make this determination based on information supplied by the applicant and such additional information as the licensing authority may acquire from the applicable jurisdiction. As relevant to the license at issue, the licensing authority may consider the following factors in determining substantial equivalence: scope of practice, education and coursework, degree requirements, experience, and examinations required for licensure.

196.3(4) The licensing authority shall promptly grant a license to the veteran or spouse if the applicant is licensed in the same or similar profession in another jurisdiction whose licensure requirements are substantially equivalent to those required in Iowa, unless the applicant is ineligible for licensure based on other grounds, for example, the applicant's disciplinary or criminal background.

196.3(5) If the licensing authority determines that the licensure requirements in the jurisdiction in which the veteran or spouse is licensed are not substantially equivalent to those required in Iowa, the licensing authority shall promptly inform the applicant of the additional experience, education, or examinations required for licensure in Iowa. Unless the applicant is ineligible for licensure based on other grounds, such as disciplinary or criminal background, or the issuance of a provisional license is inconsistent with the licensing authority's enabling statute, the following shall apply:

a. If an applicant has not passed the required examination(s) for licensure, the applicant may not be issued a provisional license but may request that the licensure application be placed in pending status for up to one year or as mutually agreed to provide the applicant with the opportunity to satisfy the examination requirements.

b. If additional experience or education is required for the applicant's qualifications to be considered substantially equivalent, the applicant may request that the licensing authority issue a provisional license for a specified period of time during which the applicant will successfully complete the necessary experience or education. The licensing authority shall issue a provisional license for a specified period of time upon such conditions as the licensing authority deems reasonably necessary to protect the health, welfare or safety of the public unless the licensing authority determines that the deficiency is of a character that the public health, welfare or safety will be adversely affected if a provisional license is granted.

c. If a request for a provisional license is denied, the licensing authority shall issue an order fully explaining the decision and shall inform the applicant of the steps the applicant may take in order to receive a provisional license.

d. If a provisional license is issued, the application for full licensure shall be placed in pending status until the necessary experience or education has been successfully completed or the provisional license expires, whichever occurs first. The licensing authority may extend a provisional license on a case-by-case basis for good cause.

196.3(6) A veteran or spouse who is aggrieved by the licensing authority's decision to deny an application for a reciprocal license or a provisional license or is aggrieved by the terms under which a provisional license will be granted may request a contested case (administrative hearing) and may participate in a contested case by telephone. A request for a contested case shall be made within 30 days of issuance of the licensing authority's decision. The provisions of 641—Chapter 173 shall apply, except that no fees or costs shall be assessed against the applicant in connection with a contested case conducted pursuant to this subrule.

[ARC 1749C, IAB 12/10/14, effective 1/14/15; ARC 5061C, IAB 6/17/20, effective 7/22/20]

These rules are intended to implement Iowa Code section 272C.4.

[Filed ARC 1749C (Notice ARC 1646C, IAB 10/1/14), IAB 12/10/14, effective 1/14/15]

[Filed ARC 5061C (Notice ARC 5000C, IAB 3/25/20), IAB 6/17/20, effective 7/22/20]

VETERINARY MEDICINE BOARD [811]

Rules renumbered and transferred from agency number[842] to [811] to conform with the reorganization numbering scheme in general.

CHAPTER 1

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CHAPTER 2

PETITIONS FOR RULE MAKING

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CHAPTER 3

DECLARATORY ORDERS

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CHAPTER 5
PUBLIC RECORDS AND FAIR INFORMATION PRACTICES

Insert the fair information practices segment of the Uniform Administrative Rules which is printed in the first volume of the Iowa Administrative Code with the addition of new rules 811—5.9(17A,22) to 811—5.16(17A,22) and the following amendments:

811—5.1(17A,22) Definitions. In lieu of the words “(official or body issuing these rules)” insert “board of veterinary medicine”.

811—5.3(17A,22) Requests for access to records.

5.3(1) Location of record. In lieu of the words “(insert agency head)”, insert “state veterinarian as secretary of the board of veterinary medicine”. In lieu of the words “(insert agency name and address)”, insert “Board of Veterinary Medicine, State Veterinarian, Department of Agriculture and Land Stewardship, Wallace State Office Building, 502 E. 9th Street, Des Moines, Iowa 50319-0053”.

5.3(2) Office hours. In lieu of the parenthetical statement, insert “8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays”.

5.3(7) Fees.

a. When charged. To the extent permitted by applicable provisions of law, the payment of fees may be waived when the imposition of fees is inequitable or when a waiver is in the public interest.

c. Supervisory fee. In lieu of the words “(specify time period)” insert “one-half hour”.

811—5.6(17A,22) Procedure by which additions, dissents, or objections may be entered into certain records. In lieu of the words “(designate office)” insert “the board of veterinary medicine”.

811—5.9(17A,22) Disclosures without the consent of the subject.

5.9(1) Open records are routinely disclosed without the consent of the subject.

5.9(2) To the extent allowed by law, disclosure of confidential records may occur without the consent of the subject. Following are instances where disclosure, if lawful, will generally occur without notice to the subject:

a. For a routine use as defined in rule 811—5.10(17A,22) or in any notice for a particular record system.

b. To a recipient who has provided the agency with advance written assurance that the record will be used solely as a statistical research or reporting record, provided that the record is transferred in a form that does not identify the subject.

c. To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if an authorized representative of such government agency or instrumentality has submitted a written request to the agency specifying the record desired and the law enforcement activity for which the record is sought.

d. To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual if a notice of the disclosure is transmitted to the last known address of the subject.

e. To the legislative services agency under Iowa Code section 2A.3.

f. Disclosures in the course of employee disciplinary proceedings.

g. In response to a court order or subpoena.

811—5.10(17A,22) Routine use.

5.10(1) Defined. “Routine use” means the disclosure of a record without the consent of the subject or subjects, for a purpose which is compatible with the purpose for which the record was collected. It includes disclosures required to be made by statute other than the public records law, Iowa Code chapter 22.

5.10(2) To the extent allowed by law, the following uses are considered routine uses of all agency records:

a. Disclosure to those officers, employees, and agents of the agency who have a need for the record in the performance of their duties. The custodian of the record may, upon request of any officer or employee, or on the custodian's own initiative, determine what constitutes legitimate need to use confidential records.

b. Disclosure of information indicating an apparent violation of the law to appropriate law enforcement authorities for investigation and possible criminal prosecution, civil court action, or regulatory order.

c. Disclosure to the department of inspections and appeals for matters in which it is performing services or functions on behalf of the agency.

d. Transfers of information within the agency, to other state agencies, or to local units of government as appropriate to administer the program for which the information is collected.

e. Information released to staff of federal and state entities for audit purposes or for purposes of determining whether the agency is operating a program lawfully.

f. Any disclosure specifically authorized by the statute under which the record was collected or maintained.

811—5.11(17A,22) Consensual disclosure of confidential records.

5.11(1) *Consent to disclosure by a subject individual.* To the extent permitted by law, the subject may consent in writing to agency disclosure of confidential records as provided in rule 811—5.7(17A,22).

5.11(2) *Complaints to public officials.* A letter from a subject of a confidential record to a public official which seeks the official's intervention on behalf of the subject in a matter that involves the agency may, to the extent permitted by law, be treated as an authorization to release sufficient information about the subject to the official to resolve the matter.

811—5.12(17A,22) Release to subject.

5.12(1) The subject of a confidential record may file a written request to review confidential records about that person as provided in rule 811—5.6(17A,22). However, the agency need not release the following records to the subject:

a. The identity of a person providing information to the agency need not be disclosed directly or indirectly to the subject of the information when the information is authorized to be held confidential pursuant to Iowa Code section 22.7(18) or other provision of law.

b. Records need not be disclosed to the subject when they are the work product of an attorney or are otherwise privileged.

c. Peace officers' investigative reports may be withheld from the subject, except as required by the Iowa Code. (See Iowa Code section 22.7(5))

d. As otherwise authorized by law.

5.12(2) Where a record has multiple subjects with interest in the confidentiality of the record, the agency may take reasonable steps to protect confidential information relating to another subject.

811—5.13(17A,22) Availability of records.

5.13(1) *General.* Agency records are open for public inspection and copying unless otherwise provided by rule or law.

5.13(2) *Confidential records.* The following records may be withheld from public inspection. Records are listed by category, according to the legal basis for withholding them from public inspection.

a. Sealed bids received prior to the time set for public opening of bids. (Iowa Code section 72.3)

b. Tax records made available to the agency. (Iowa Code sections 422.20 and 422.72)

c. Records which are exempt from disclosure under Iowa Code section 22.7.

d. Minutes of closed meetings of a government body. (Iowa Code section 21.5(4))

e. Identifying details in final orders, decisions and opinions to the extent required to prevent a clearly unwarranted invasion of personal privacy or trade secrets under Iowa Code section 17A.3(1) "d."

f. Those portions of agency staff manuals, instructions or other statements issued which set forth criteria or guidelines to be used by agency staff in auditing, in making inspections, in settling commercial disputes or negotiating commercial arrangements, or in the selection or handling of cases, such as operational tactics or allowable tolerances or criteria for the defense, prosecution or settlement of cases, when disclosure of these statements would:

- (1) Enable law violators to avoid detection;
- (2) Facilitate disregard of requirements imposed by law; or
- (3) Give a clearly improper advantage to persons who are in an adverse position to the agency. (See Iowa Code sections 17A.2 and 17A.3)

g. Records which constitute attorney work product, attorney-client communications, or which are otherwise privileged. Attorney work product is confidential under Iowa Code sections 22.7(4), 622.10 and 622.11, Iowa R.C.P. 122(c), Fed. R. Civ. P. 26(b)(3), and case law. Attorney-client communications are confidential under Iowa Code sections 622.10 and 622.11, the rules of evidence, the Code of Professional Responsibility, and case law.

h. Any other records made confidential by law.

5.13(3) Authority to release confidential records. The agency may have discretion to disclose some confidential records which are exempt from disclosure under Iowa Code section 22.7 or other law. Any person may request permission to inspect records withheld from inspection under a statute which authorizes limited or discretionary disclosure as provided in rule 811—5.4(17A,22). If the agency initially determines that it will release such records, the agency may, where appropriate, notify interested parties and withhold the records from inspection as provided in subrule 5.4(3).

811—5.14(17A,22) Personally identifiable information. This rule describes the nature and extent of personally identifiable information which is collected, maintained, and retrieved by the agency by personal identifier in record systems as defined in rule 811—5.1(17A,22). For each record system, this rule describes the legal authority for the collection of that information, the means of storage of that information and indicates whether a data processing system matches, collates, or permits the comparison of personally identifiable information in one record system with personally identifiable information in another record system. Unless otherwise stated, the authority for this agency to maintain the record is provided by Iowa Code chapter 169. The record systems maintained by the agency are:

5.14(1) Personnel files. “Employees” of the agency are employed through the department of agriculture and land stewardship. Through the department of agriculture and land stewardship, the agency maintains files containing information about “employees,” families and dependents, and applicants for positions with the agency. The files include payroll records, biographical information, medical information relating to disability, performance reviews and evaluations, disciplinary information, information required for tax withholding, information concerning employee benefits, affirmative action reports, and other information concerning the employer-employee relationship. This material includes personally identifiable information such as name, address, social security number and employee payroll number. Some of this information is confidential under Iowa Code section 22.7(11). These records are primarily maintained in paper copy, with some material generated or maintained in a data processing system.

5.14(2) Litigation files. These files or records contain information regarding litigation or anticipated litigation, which includes judicial and administrative proceedings. The records include briefs, depositions, docket sheets, documents, correspondence, attorneys’ notes, memoranda, research materials, witness information, investigation materials, information compiled under the direction of the attorney, and case management records. The files contain materials which are confidential as attorney work product and attorney-client communications. Some materials are confidential under other applicable provisions of law or because of a court order. Persons wishing copies of pleadings and other documents filed in litigation should obtain these from the clerk of the appropriate court which maintains the official copy. These records are primarily maintained in paper copy, with some material generated or maintained in a data processing system.

5.14(3) Contested case matters. These records are collected and maintained pursuant to Iowa Code sections 17A.3(1) “d,” 17A.3(2), and 17A.12, and the Iowa Code sections noted in subrule 5.14(4). Contested case matters include all pleadings, motions, briefs, orders, transcripts, exhibits, and physical evidence utilized in the resolution of the matter, and may, unless released by the credential holder, be confidential as stated in subrule 5.14(4). These records are primarily maintained in paper copy, with some material generated or maintained in a data processing system.

5.14(4) Credential records. Under Iowa Code chapter 169, the board regulates by license veterinarians, and regulates by certificate veterinary technicians, assistants and veterinary students, and regulates by temporary permit veterinarians credentialed under Iowa Code section 169.11 and rule 811—9.1(169), Iowa Administrative Code. Credential records include, but are not limited to, information identifying the credential holder by name or code, location, and form of business entity, including the names of corporate principals. These records may include examinations, complaints, compliance activities and investigatory reports that are confidential. These records may include confidential information protected from disclosure under Iowa Code sections 22.7, 169.6 and 272.6. These records are maintained jointly with the department of agriculture and land stewardship. These records are primarily maintained in paper copy, with some material generated or maintained in a data processing system.

5.14(5) Laboratory reports. In furtherance of licensure and certification regulation under subrule 5.14(4), the board may procure laboratory reports consisting of analytical results of samples. These records may include confidential information protected from disclosure under Iowa Code section 22.7(3), 22.7(6), or 22.7(18), as well as those provisions stated in subrule 5.14(4). These records are primarily maintained in paper copy, with some material generated or maintained in a data processing system. These records are identified by the name or code of the subject of the investigation.

811—5.15(17A,22) Other groups of records. This rule describes groups of records maintained by the agency other than record systems as defined in rule 811—5.1(17A,22). These records are routinely available to the public. However, the agency’s files of these records may contain confidential information as discussed in rule 811—5.13(17A,22). The records listed may contain information about individuals.

1. Administrative records. This includes documents concerning budget, property inventory, purchasing, yearly reports, office policies for employees, time sheets, printing and supply requisitions.

2. Publications. The office receives a number of books, periodicals, newsletters, government documents, etc. These materials would generally be open to the public but may be protected by copyright law. Most publications of general interest are available in the state law library.

3. Rule-making records. Public documents generated during the promulgation of agency rules, including notices and public comments, are available for public inspection.

4. Board records. Agendas, minutes, and materials prepared or maintained by the board are available from the office, except those records concerning closed sessions which are exempt from disclosure under Iowa Code section 21.5 or which are otherwise confidential by law. Board records contain information about people who participate in meetings. This information is collected pursuant to Iowa Code section 21.3. This information is not stored on an automated data processing system.

5. All other records that are not exempted from disclosure by law.

811—5.16(17A,22) Data processing systems. None of the data processing systems used by the agency permit the comparison of personally identifiable information in one record system with personally identifiable information in another record system.

811—5.17(169,252J,272D) Release of confidential licensing information for collection purposes. Notwithstanding any statutory confidentiality provision, the board may share information with the child support recovery unit or with the centralized collection unit of the department of revenue through manual or automated means for the sole purpose of identifying applicants or credential holders subject to enforcement under Iowa Code chapter 252J, 598 or 272D.

[ARC 9512B, IAB 5/18/11, effective 6/22/11]

811—5.18(17A,22,169,261) Release of information to the college student aid commission. Rescinded ARC 5062C, IAB 6/17/20, effective 7/22/20.

These rules are intended to implement Iowa Code chapters 17A, 22, 169 and 252J.

[Filed 3/2/78, Notice 9/21/77—published 3/22/78, effective 4/26/78]

[Filed 1/20/89, Notice 11/16/88—published 2/8/89, effective 3/15/89]

[Filed 8/9/96, Notice 5/22/96—published 8/28/96, effective 10/2/96]

[Filed 10/27/98, Notice 9/9/98—published 11/18/98, effective 12/23/98]

[Filed 9/4/08, Notices 4/23/08, 6/18/08—published 9/24/08, effective 10/29/08]

[Filed ARC 9512B (Notice ARC 9429B, IAB 3/23/11), IAB 5/18/11, effective 6/22/11]

[Filed ARC 5062C (Notice ARC 5013C, IAB 3/25/20), IAB 6/17/20, effective 7/22/20]

CHAPTER 6
APPLICATION FOR VETERINARY LICENSURE

[Prior to 2/8/89, Veterinary Medicine, Board of[842] Ch 2]

Chapter 6, Suspension or Revocation of License, rescinded IAC 2/8/89; see 811—Ch 10.

811—6.1(169) Procedure.

6.1(1) *Application to take examination.* Any person desiring to take the NAVLE in Iowa for a license to practice veterinary medicine shall make application to the board in accordance with the guidelines and time lines established by the NBVME. The applicant shall submit to the board proof of completing the application process with NBVME along with the administrative fee by sending the proof and fee to:

Iowa Board of Veterinary Medicine
Iowa Department of Agriculture and Land Stewardship
Wallace State Office Building
502 E. 9th Street
Des Moines, Iowa 50319-0053

Proof of NAVLE application shall be submitted to the board in accordance with the guidelines and time lines established by the NBVME on forms to be provided by the board. The form shall be notarized and completely filled out. The completed form shall include one current passport size and quality photograph of the applicant. Incomplete applications shall be returned to the applicant along with the tendered fee and a written statement setting forth the reasons for such rejections.

The form shall be accompanied by satisfactory evidence of the applicant's having graduated from an AVMA-accredited school of veterinary medicine or satisfactory evidence that the applicant is expected to graduate within six months of the date of the examination.

Applications to take the NAVLE will not be accepted from any person who has previously taken and passed that examination in any jurisdiction, except on case-by-case petition to the board for good cause shown or other order of the board.

6.1(2) *License requirements.* Prior to the board's issuance of a license, the applicant shall:

- a. Successfully complete the NAVLE as provided in rule 811—7.1(169);
- b. Remit the proper application fee for licensure;
- c. Graduate from:
 - (1) An AVMA-accredited school of veterinary medicine; or
 - (2) An AVMA-listed school of veterinary medicine and have received a certificate from either ECFVG or PAVE;
- d. Provide a statement indicating all jurisdictions in which the applicant is or has ever been licensed to practice veterinary medicine. The applicant shall provide information and shall consent to release to the board license information from jurisdictions in which the applicant is or has ever been licensed;
- e. Provide information or consent to the release of information pertinent to the character and education of the applicant as the board may deem necessary in order to evaluate the applicant's qualifications; and
- f. Submit evidence of having completed at least 60 hours of approved continuing education within the last three licensing years. New graduates and applicants within one year after the date of graduation are exempt from continuing education requirements for initial licensing. Applicants who apply more than one year but less than two years after the date of graduation must complete at least 20 hours of approved continuing education. Applicants who apply more than two years but less than three years after the date of graduation must have completed at least 40 hours of approved continuing education. As used in this paragraph, "date of graduation" also includes the date of PAVE or ECFVG certification.

A license issued during a triennium, upon the applicant's completion of these requirements and payment of the prorated triennial license fee, shall be issued for the balance of the triennium. A license shall expire on June 30 of the third year if the triennium.

811—6.2(169) Fee schedule for veterinarians. The following fees shall be collected by the board and shall not be refunded except by board action in unusual instances such as documented illness of the

applicant, death of the applicant, inability of the applicant to comply with the rules of the board, or withdrawal of an examination application provided withdrawal is received in writing 45 days prior to the examination date. However, the state fees may be waived for qualifying military service personnel upon request. Examination fees shall be nontransferable from one examination to another.

The fee for the NAVLE, which is utilized by the board as a part of the licensure process, shall be the fee charged that year by NBVME, plus an administrative fee payable to the board.

Based on the board’s anticipated financial requirements, the following fees are hereby adopted:

License—application fee	\$50
NAVLE examination fee	set by NBVME
Board administrative fee for NAVLE.	\$25
State veterinary examination fee	set by board
State veterinary administration fee	set by board
Triennial license	\$60
Late renewal penalty	\$100
License by endorsement—application fee	\$50
Reactivation fee for lapsed or inactive license	\$100
Reinstatement fee	\$100
Duplicate license.	\$15
Temporary permit	\$35
Temporary permit application fee	\$15
Official licensure verification	\$15
Charge for insufficient funds or returned checks.	\$25
Senior student certificate	\$0

This rule is intended to implement Iowa Code sections 169.5 and 169.12.
[ARC 1984C, IAB 4/29/15, effective 6/3/15]

811—6.3(169) Reactivation fee. All applications for reactivation of a lapsed or inactive license to practice veterinary medicine shall be filed with the secretary of the board, together with the then current license fee, the current reactivation fee, and all applicable penalties for a lapsed or inactive license.

811—6.4(169) Graduates of foreign schools. Graduates of foreign veterinary schools may become eligible for examination and licensure by either of the following methods:

6.4(1) Examination eligibility through ECFVG. Graduates of foreign veterinary schools which, pursuant to the AVMA criteria, are not AVMA-accredited but are AVMA-listed may make application to take the NAVLE in this state provided that the application includes a copy of the applicant’s diploma or certificate indicating the award of a degree in veterinary medicine from an AVMA-listed college and a letter from the ECFVG verifying that the applicant is or will be participating in an ECFVG certification program.

6.4(2) Licensure eligibility through ECFVG. Graduates of foreign veterinary schools which are not AVMA-accredited but are AVMA-listed will not be considered for licensing until they have received the certificate granted by the ECFVG. A license will not be issued to an applicant until the applicant submits a certified copy of the applicant’s ECFVG certificate.

6.4(3) Examination eligibility through PAVE. Graduates of foreign veterinary schools may make application to take the NAVLE in this state provided that the application includes a certified copy of the applicant’s diploma or certificate indicating the award of a degree in veterinary medicine from a foreign veterinary school and a letter from the AAVSB on behalf of PAVE verifying that the applicant is participating in the PAVE certification program administered by the AAVSB, and has met the requirements for taking the NAVLE.

6.4(4) *Licensure eligibility through PAVE.* Graduates of foreign veterinary schools will not be considered for licensing until they have received the certificate granted by PAVE. A license will not be issued to an applicant until the applicant submits a copy of the applicant's PAVE certificate.

811—6.5(169) License by endorsement.

6.5(1) A license by endorsement may be granted by the board pursuant to either Iowa Code section 169.10(1) or 169.10(2). An applicant shall make application for a license by endorsement on a form provided by the board. The application fee and triennial license fee shall accompany the application. In addition to the information specified in Iowa Code section 169.10, the applicant shall supply all of the following:

a. A statement indicating all jurisdictions in which the licensee is or has ever been licensed to practice veterinary medicine. The applicant shall provide information and shall consent to the release of information to the board from jurisdictions in which the applicant is or has ever been licensed.

b. Information pertinent to the character and education of the applicant as the board may deem necessary in order to evaluate the applicant's qualifications.

c. Evidence of approved continuing education totaling at least 60 hours obtained within the last three licensing years. New graduates and applicants within one year after graduation are exempt from continuing education requirements for initial licensing. Applicants who apply more than one year but less than two years after the date of graduation must complete at least 20 hours of approved continuing education. Applicants who apply more than two years but less than three years after the date of graduation must have completed at least 40 hours of approved continuing education. As used in this paragraph, "date of graduation" also includes the date of PAVE or ECFVG certification. Foreign graduates licensed by PAVE or ECFVG certification are exempt from the continuing education requirement for one year from the date of certification by PAVE or ECFVG.

6.5(2) For an applicant with a non-Iowa license seeking licensure under Iowa Code section 169.10(1), the following shall apply:

a. If the applicant's non-Iowa license was issued between December 31, 1964, and December 31, 1979, the applicant shall have successfully completed the National Board Examination (NBE).

b. If the applicant's non-Iowa license was issued between January 1, 1980, and December 31, 2000, the applicant shall have successfully completed the National Board Examination (NBE) and the Clinical Competency Test (CCT).

c. If the applicant's non-Iowa license was issued on or after January 1, 2001, the applicant shall have successfully completed the NAVLE in accordance with rule 811—7.1(169).

6.5(3) An applicant who is a diplomate under Iowa Code section 169.10(2) shall also include a copy of the applicant's board or college specialty certificate. For the purpose of this rule, a specialty board or college means a specialty board or college which has been officially recognized by the AVMA. Changes of specialty status shall be reported to the board within 30 days of the action.

811—6.6(169) Issuance of limited license; specialization.

6.6(1) The board may grant a license to practice veterinary medicine within a limited and specified scope:

a. As an option for board discipline under 811—Chapter 10.

b. To a qualified member of the faculty of the Iowa State University College of Veterinary Medicine.

c. To an applicant requesting limited or specialized status.

6.6(2) A licensed veterinarian shall not claim or imply specialization unless the veterinarian is a diplomate in good standing of the respective specialty board or college recognized by the AVMA.

6.6(3) Veterinary student certificate. The board may issue a veterinary student certificate to a senior veterinary student who is attending an AVMA-accredited college of veterinary medicine, upon endorsement by the college that the student is competent to perform veterinary duties. The certificate issued by the board shall limit the student to performing duties under the direction of an instructor of veterinary medicine or under the direct supervision of a licensed veterinarian. Veterinary student

certificate holders are prohibited from administering rabies vaccine to dogs as described in Iowa Code section 351.35 and signing a certificate of veterinary inspection as described in Iowa Code section 163.12.

6.6(4) Limited licensure for faculty. Faculty, not including residents or interns, at Iowa State University College of Veterinary Medicine may be issued a limited license to practice veterinary medicine. The applicant for a limited license for faculty shall have graduated from an AVMA-accredited or AVMA-listed school of veterinary medicine or have received a PAVE or ECFVG certificate and shall submit a completed application and the required fees. Holders of limited licenses for faculty are limited to duties performed on the college premises during periods of employment at the college.

811—6.7(169) License renewal.

6.7(1) A license to practice veterinary medicine shall be issued for a three-year period, except that new licenses issued during a triennium shall be issued for the balance of that triennium, except that new certificates issued during a triennium shall be issued for the balance of the triennium and the certificate fee shall be prorated. A license shall expire on June 30 of the third year of the triennium.

6.7(2) At least two months before the end of a triennium, a renewal notice will be sent to each licensee at the last address in the board's file. Failure to receive the notice shall not relieve the licensee of the obligation to pay triennium renewal fees on or before June 30.

6.7(3) The license renewal application shall include a statement which certifies the jurisdictions in which the licensee is currently or has in the past been licensed to practice veterinary medicine.

6.7(4) Renewal fees shall be received by the board on or before the end of the triennium on June 30. Whenever renewal fees are not received as specified, the license lapses and the practice of veterinary medicine must cease until all renewal fees and penalty fees are received by the board.

6.7(5) If the renewal fee has not been received by the board before the license has lapsed, an application for renewal must be filed with the board with a renewal fee in addition to the reactivation fee and the late renewal penalty fee.

811—6.8(169,261) Issuance or renewal of a license to practice veterinary medicine—denial. Rescinded **ARC 5062C**, IAB 6/17/20, effective 7/22/20.

811—6.9(169) Renewal, lapsed or inactive license. A veterinarian whose license has lapsed may renew an expired license within five years of the date of its expiration by making written application for renewal and paying the current renewal fee plus all delinquent renewal fees. After five years have elapsed since the date of expiration, a license may not be renewed, and the veterinarian must make application for a new license and take the license examination. A veterinarian whose license has lapsed or has been placed on inactive status shall, prior to receiving active status licensure in the practice of veterinary medicine in the state of Iowa, satisfy the requirements in either subrule 6.9(1) or subrule 6.9(2) for renewal of a lapsed or inactive license:

6.9(1) *Renewal of a lapsed or inactive license.* An applicant for renewal of a lapsed or inactive license shall do both of the following:

a. Submit written application for renewal of a lapsed or inactive license to the board upon forms provided by the board;

b. Furnish evidence of compliance with continuing education requirements specified in rule 811—11.3(169).

6.9(2) *Renewal by endorsement.* An applicant for renewal by endorsement may submit an application for renewal by endorsement by following the procedures set out in rule 811—6.5(169).

These rules are intended to implement Iowa Code chapters 17A and 169.

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CHAPTER 10
DISCIPLINE

[Prior to 2/8/89, see Veterinary Medicine, Board of[842] Ch 6]

811—10.1(17A,169,272C) Board authority. The board may discipline any credential holder for any grounds stated in Iowa Code chapters 169 and 272C or rules promulgated thereunder.

811—10.2(17A,169,272C) Complaints and investigations. Complaints are allegations of wrongful acts or omissions relating to the ethical or professional conduct of a credential holder.

10.2(1) In accordance with Iowa Code section 272C.3(1)“c,” the board shall investigate or review, upon written complaint or upon its own motion pursuant to other information received by the board, alleged acts or omissions which the board reasonably believes constitute cause for credential holder discipline.

10.2(2) The executive secretary or authorized designee shall investigate complaints in order to determine the probability that a violation of law or rule has occurred.

811—10.3(17A,169,272C) Investigatory subpoena powers. The board shall have the authority to issue an investigatory subpoena in accordance with the provisions of Iowa Code section 17A.13.

10.3(1) A subpoena which requires production of real evidence that is necessary to an investigation may be issued upon the authority of the executive secretary or a designee.

10.3(2) Any person who is aggrieved or adversely affected by compliance with the subpoena and who desires to challenge the subpoena must, within 14 days after the service of the subpoena or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified and may be accompanied by legal briefs or factual affidavits.

10.3(3) In the event obedience to a subpoena is refused, the requesting party may petition the district court for enforcement.

811—10.4(17A,169,272C) Board action. The board shall review investigative conclusions and take one of the following actions:

1. Close the investigative case without action.
2. Request further inquiry.
3. Appoint a peer review committee to assist with the investigation.
4. Determine the existence of sufficient probable cause and order a disciplinary hearing to be held in compliance with Iowa Code section 272C.6.

811—10.5(17A,169,272C) Peer review committee. The board may establish a peer review committee to assist with the investigative process when deemed necessary.

10.5(1) The committee shall determine if the conduct of the credential holder conforms to minimum standards of acceptable and prevailing practice of veterinary medicine or other applicable standards and submit a report of its findings to the board.

10.5(2) The board shall review the committee’s findings and proceed with action available under rule 10.4(17A,169,272C).

10.5(3) The peer review committee shall observe the confidentiality requirements imposed by Iowa Code section 272C.6.

811—10.6(17A,169,272C) Grounds for discipline. Without regard as to whether the board has determined that an injury has occurred, the board may impose any of the disciplinary sanctions set forth in rule 10.7(17A,169,272C), including civil penalties in an amount not to exceed \$10,000, when the board determines that the credential holder is guilty of any of the following acts or offenses:

10.6(1) *Grounds applicable to all credential holders.*

a. Fraud in procuring a credential, which includes but is not limited to an intentional perversion of the truth in making application for a credential to practice any of the professions or activities regulated

by the board in this state, and includes false representations of a material fact, whether by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a credential in this state, or attempting to file or filing with the board or the Iowa department of agriculture and land stewardship any false or forged diploma, certificate, affidavit, identification, or qualification in making an application for a credential in this state.

b. Credential holder professional incompetency. Professional incompetency of a credential holder may be established by:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the credential holder's practice.

(2) A substantial deviation by the credential holder from the standards of learning or skill ordinarily possessed and applied by other credential holders acting in the same or similar circumstances.

(3) A willful or repeated departure from or the failure to conform to the minimal standards of acceptable and prevailing practice of credential holders.

(4) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession or engaging in unethical conduct or practice harmful or detrimental to the public.

1. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession includes, but is not limited to, an intentional perversion of the truth, either orally or in writing, and includes any representation contrary to legal or equitable duty, trust or confidence and is deemed by the board to be contrary to good conscience, prejudicial to the public welfare or may operate to the injury of another.

2. Practice harmful or detrimental to the public includes, but is not limited to, the failure of a credential holder to possess and exercise that degree of skill, learning and care expected of a reasonable, prudent credential holder acting in the same or similar circumstances, including for a veterinarian a violation of the standards of practice as set out in 811—Chapter 12, or when a credential holder is unable to practice with reasonable skill and safety on a client's animals as a result of a mental or physical impairment or chemical abuse.

(5) Habitual intoxication or addiction to the use of drugs, which includes, but is not limited to, the inability of a credential holder to practice with reasonable skill and safety by reason of the excessive use of alcohol, drugs, narcotics, chemicals or other types of material on a continuing basis, or the excessive use of alcohol, drugs, narcotics, chemicals or other types of material which may impair a credential holder's ability to practice with reasonable skill and safety. The board may require a credential holder's completion of a treatment program as a condition of probation or suspension, and shall consider the credential holder's willingness to complete a treatment program when determining the appropriate degree of disciplinary sanction.

(6) Conviction of a felony which is either of the following:

1. One that is related to the credential holder's profession or occupation; or

2. One that would affect the credential holder's ability to practice within the profession.

Conviction of a felony related to the profession or occupation of the credential holder or the conviction of any felony that would affect the credential holder's ability to practice within the profession includes, but is not limited to, the conviction of a public offense in the practice of the credential holder's profession which is defined or classified as a felony under state or federal law, or violation of a statute or law designated as a felony in this state, another state, or the United States, which statute or law relates to the credential holder's profession or conviction of a felonious act, which is so contrary to honesty, justice or good morals, and so reprehensible as to violate the public confidence and trust imposed upon a credential holder in this state. A copy of the record of conviction or plea of guilty shall be conclusive evidence.

(7) Fraud in representations as to skill or ability, which includes but is not limited to a credential holder's having made misleading, deceptive or untrue representations as to the credential holder's competency to perform professional services for which the credential holder is not qualified to perform by training or experience.

(8) Use of untruthful or improbable statements in advertisements, which includes but is not limited to an action by a credential holder in making information or intention known to the public which is false,

deceptive, misleading or promoted through fraud or misrepresentation and includes statements which may consist of, but not be limited to:

1. Inflated or unjustified expectations of favorable results;
2. Self-laudatory claims that imply that the credential holder engaged in a field or specialty of practice for which the credential holder is not qualified. A veterinarian is not qualified to claim or imply specialization unless the veterinarian is a member in good standing of the respective specialty board or college recognized by the AVMA;

3. Representations that are likely to cause the average person to misunderstand; or
4. Extravagant claims or claims of extraordinary skills not recognized by the credential holder's profession.

(9) Willful or repeated violations of the provisions of Iowa Code chapters 169 and 272C and rules promulgated thereunder by the board.

(10) Violating a statute or law of this state, another state, or the United States, without regard to its designation as either felony or misdemeanor, which statute or law relates to the practice of veterinary medicine.

(11) Failure to report a license, certificate, permit, or other credential revocation, suspension or other disciplinary action taken by a licensing or regulating authority of another state, territory or country within 30 days of the final action by such licensing or regulating authority. A stay by an appellate court shall not negate this requirement; however, if such disciplinary action is overturned or reversed by a court of last resort, such report shall be expunged from the records of the board.

(12) Failure of a credential holder or an applicant for a credential in this state to report, within 30 days, any of the following:

1. Any settlement agreement or voluntary agreement to restrict the practice of veterinary medicine or other applicable activities entered into in another state, district, territory or country; or
2. Any adverse judgment in a malpractice action to which the credential holder is a party; or
3. Any settlement of a claim against the credential holder alleging malpractice.

(13) Knowingly aiding, assisting, procuring, or advising a person to unlawfully practice veterinary medicine.

(14) Inability to perform duties for which a credential is required with reasonable skill and safety by reason of a mental or physical impairment.

(15) Violating a lawful order of the board previously entered by the board in a disciplinary hearing.

(16) Being adjudged mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a credential for the duration of the credential unless the board orders otherwise.

(17) Knowingly submitting a false report of continuing education or failure to submit the triennial report of continuing education.

(18) Failure to comply with a subpoena issued by the board.

(19) Willful or gross negligence.

(20) Obtaining any fee by fraud or misrepresentation.

(21) Violating any of the grounds for the revocation or suspension of a credential as listed in Iowa Code section 169.13 or these rules.

(22) Having the person's certificate, license, permit, or other credential revoked or suspended, or having any other disciplinary action taken by a licensing or regulating authority of another state, territory, country, or the United States Department of Agriculture (USDA), or having the veterinarian's USDA accreditation revoked, suspended or other disciplinary action taken against the accreditation. A certified copy of the record or order of suspension, revocation, or disciplinary action is conclusive evidence of the credential holder's having committed one of the following actions:

1. Permitting or directing any auxiliary personnel or any other person who does not hold the proper credentials to perform veterinary duties involving diagnosis, prescription or surgery, except as allowed pursuant to rule 811—8.5(169);

2. Permitting or directing any auxiliary personnel or any other person to perform any act which would be a legal or ethical violation if committed by a veterinarian;

3. Failing to comply with a lawful child support order as provided in 811—Chapter 13; or
4. Failing to pay any hearing fees and costs within the time specified in the board's decision;
- c. The board shall not suspend or revoke a license issued by the board to a person who is in default or is delinquent on repayment or a service obligation under federal or state postsecondary educational loans or public or private services-conditional postsecondary tuition assistance solely on the basis of such default or delinquency.

10.6(2) Grounds applicable to licensed veterinarians only. In addition to the grounds set out in subrule 10.6(1), without regard as to whether the board has determined that injury has occurred, a licensed veterinarian is subject to disciplinary action for the violation of any of the following:

a. Engaging in unethical conduct which includes, but is not limited to, a violation of the standards of practice as set out in 811—Chapter 12, and which may include acts or offenses in violation of the AVMA Principles of Veterinary Medical Ethics.

b. Engaging in practice harmful or detrimental to the public which includes, but is not limited to, either of the following:

(1) The use of a rubber stamp to affix a signature to a prescription. A licensee who is unable, due to a physical disability, to make a written signature or mark may substitute in lieu of a signature a rubber stamp which is adopted by the disabled person for all purposes requiring a signature and which is affixed by the disabled person or affixed by another person upon the request of the disabled person and in the licensee's presence.

(2) The practice of maintaining any presigned prescription which is intended to be completed and issued at a later time.

c. Willfully or repeatedly departing from, or failing to conform to, the minimal standard of acceptable and prevailing practice of veterinary medicine which includes, but is not limited to, a violation of the standards of practice as set out in 811—Chapter 12; or committing an act contrary to honesty, justice or good morals, whether the act is committed in the course of practice or otherwise, and whether the act is committed within or without this state, where such act substantially relates to the practice of veterinary medicine. It is not necessary for grounds to exist under this paragraph that actual injury to a patient be established.

d. Indiscriminately or promiscuously prescribing, administering or dispensing any drug; or prescribing, administering or dispensing any drug for other than a lawful purpose.

e. Negligently failing to exercise due care in the delegation of veterinary services to or in supervision of employees or other individuals, whether or not injury results.

[ARC 5062C, IAB 6/17/20, effective 7/22/20]

811—10.7(17A,169,272C) Sanctions. The board has authority to impose the following disciplinary sanctions:

1. Revoke a credential.
2. Suspend a credential until further order of the board or for a specified period.
3. Prohibit permanently, until further order of the board or for a specified period, the engaging in specified procedures, methods or acts.
4. Impose a period of probation.
5. Require additional education or training.
6. Require a reexamination.
7. Order a physical or mental examination.
8. Impose civil penalties not to exceed \$10,000.
9. Issue a citation and warning.
10. Impose such other sanctions allowed by law as may be appropriate.

811—10.8(17A,169,272C) Panel of specialists. The board may appoint a panel of veterinarians who are specialists to ascertain the facts of a case pursuant to Iowa Code section 272C.6(2). The board chairperson or designee shall appoint the presiding officer.

10.8(1) The executive secretary shall set the date, time, and location of the hearing and make proper notification to all parties.

10.8(2) The panel of specialists shall:

- a.* Enter into the record the names of the presiding officer, members of the panel, the parties and their representatives.
- b.* Enter into the record the notice and evidence of service, order for hearing, statement of charges, answer, if available, and any other pleadings, motions or orders.
- c.* Receive opening statements from the parties.
- d.* Receive evidence, in accordance with Iowa Code section 17A.14, on behalf of the state of Iowa and on behalf of the credential holder.
- e.* Question the witnesses.
- f.* Receive closing statements from the parties.
- g.* Determine the findings of fact by a majority vote and make a written report of its findings to the board within a reasonable period.

811—10.9(17A,169,272C) Informal settlement. Pursuant to the provisions of Iowa Code sections 17A.12 and 272C.3, the board may consider resolution of disciplinary matters through informal settlement prior to commencement of contested case proceedings. The secretary or designee may negotiate with the credential holder regarding a proposed disposition of the controversy. Upon consent of both parties, the board will review the proposal for action.

811—10.10(17A,169,272C) Voluntary surrender. A voluntary surrender of credentials may be submitted to the board as resolution of a contested case or in lieu of continued compliance with a disciplinary decision of the board.

811—10.11(17A,169,272C) Application for reinstatement. A person whose credential has been suspended, revoked, or voluntarily surrendered may apply to the board for reinstatement in accordance with the terms and conditions of the order.

10.11(1) If the credential was voluntarily surrendered, or if the order for suspension or revocation did not establish terms and conditions for reinstatement, an initial application may not be made until one year has elapsed from the date of the order.

10.11(2) The application shall allege facts and circumstances which will enable the board to determine that the basis for the sanction or voluntary surrender no longer exists, and that it is in the public interest to reinstate the credential. The burden of proof to establish these facts shall rest with the petitioner.

10.11(3) The hearing in an application for reinstatement is a contested case within the meaning of Iowa Code section 17A.12.

10.11(4) The order to grant or deny reinstatement shall incorporate findings of fact and conclusions of law. If reinstatement is granted, terms and conditions for reinstating the credential may be imposed.

811—10.12 Reserved.

811—10.13(17A,169,272C) Contested case proceedings. The following rules apply to board activities which are initiated upon determination of probable cause and result in the issuance of a notice of hearing.

811—10.14(17A) Definitions. Except where otherwise specifically defined by law:

“Contested case” means a proceeding defined by Iowa Code section 17A.2(5).

“Issuance” means the date of mailing of a decision or order or date of delivery if service is by other means, unless another date is specified in the order.

“Party” means each person or agency named or admitted as a party or properly seeking and entitled as of right to be admitted as a party.

“Presiding officer” means the chairperson of the board or designee.

“*Proposed decision*” means the presiding officer’s recommended findings of fact, conclusions of law, decision, and order in a contested case in which the board did not preside.

811—10.15(17A) Time requirements.

10.15(1) Time shall be computed as provided in Iowa Code subsection 4.1(34).

10.15(2) For good cause, the presiding officer may extend or shorten the time to take any action, except as precluded by statute. Except for good cause stated in the record, before extending or shortening the time to take any action, the presiding officer shall afford all parties an opportunity to be heard or to file written arguments.

811—10.16(17A) Notice of hearing. The board shall issue an order, notice of hearing, and statement of charges following its determination of probable cause pursuant to Iowa Code section 17A.12(2). Delivery of the notice of hearing constitutes the commencement of the contested case proceeding.

10.16(1) The date, time, and location of the hearing shall be set by the board. The credential holder shall be notified at least 30 days prior to the scheduled hearing.

10.16(2) Notification shall be in writing delivered either by personal service as in civil actions or by certified mail with return receipt requested. When the credential holder cannot be located:

a. An affidavit shall be prepared outlining the measures taken to attempt service, and shall become a part of the record when a notice cannot be delivered by personal service or certified mail, return receipt requested.

b. Notice of hearing shall be published once each week for three consecutive weeks in a newspaper of general circulation, published or circulated in the county of last-known residence of the credential holder. The newspaper will be selected by the secretary or designee. The first notice of hearing shall be published at least 30 days prior to the scheduled hearing.

811—10.17(17A) Presiding officer. Disciplinary hearings shall be conducted by the board pursuant to Iowa Code section 272C.6. The chairperson of the board shall designate the presiding officer in accordance with the provisions of Iowa Code section 17A.11.

10.17(1) For nondisciplinary proceedings, any party who wishes to request that the presiding officer assigned to render a proposed decision be an administrative law judge employed by the department of inspections and appeals must file a written request within 20 days after service of a notice of hearing.

10.17(2) The executive secretary may deny the request upon a finding that one or more of the following apply:

a. Neither the agency nor any officer of the agency under whose authority the contested case is to take place is a named party to the proceeding or a real party in interest to that proceeding.

b. There is a compelling need to expedite issuance of a final decision in order to protect the public health, safety, or welfare.

c. The case involves significant policy issues of first impression that are inextricably intertwined with the factual issues presented.

d. The demeanor of the witness is likely to be dispositive in resolving the disputed factual issues.

e. Funds are unavailable to pay the costs of an administrative law judge and an interagency appeal.

f. The request was not timely filed.

g. The request is not consistent with a specified statute.

h. The request would not conform to the disciplinary hearing provision of Iowa Code section 272C.6.

10.17(3) The agency (or its designee) shall issue a written ruling specifying the grounds for its decision within 20 days after a request for an administrative law judge is filed.

10.17(4) All rulings by an administrative law judge are subject to appeal to the agency. A party must seek any available intra-agency appeal in order to exhaust adequate administrative remedies.

10.17(5) Unless otherwise provided by law, the board, when reviewing a proposed decision upon intra-agency appeal, shall have the powers of and shall comply with the provisions of this chapter which apply to presiding officers.

811—10.18(17A) Waiver of procedures. Unless otherwise precluded by law, the parties in a contested case proceeding may waive any provision of this chapter. However, the agency in its discretion may refuse to give effect to such a waiver when it deems the waiver to be inconsistent with the public interest.

811—10.19(17A) Telephone proceedings. The presiding officer may resolve preliminary procedural motions by telephone conference in which all parties have an opportunity to participate. Other telephone proceedings may be held with the consent of all parties. The presiding officer will determine the location of the parties and witnesses for telephone hearings. The convenience of the witnesses or parties, as well as the nature of the case, will be considered when location is chosen.

811—10.20(17A) Disqualification.

10.20(1) A presiding officer or other person shall withdraw from participation in the making of any proposed or final decision in a contested case if that person:

- a.* Has a personal bias or prejudice concerning a party or a representative of a party;
- b.* Has personally investigated, prosecuted or advocated in connection with that case, the specific controversy underlying that case, another pending factually related contested case, or a pending factually related controversy that may culminate in a contested case involving the same parties;
- c.* Is subject to the authority, direction or discretion of any person who has personally investigated, prosecuted or advocated in connection with that contested case, the specific controversy underlying that contested case, or a pending factually related contested case or controversy involving the same parties;
- d.* Has acted as counsel to any person who is a private party to that proceeding within the past two years;
- e.* Has a personal financial interest in the outcome of the case or any other significant personal interest that could be substantially affected by the outcome of the case;
- f.* Has a spouse or relative within the third degree of relationship that: (1) is a party to the case, or an officer, secretary or trustee of a party; (2) is a lawyer in the case; (3) is known to have an interest that could be substantially affected by the outcome of the case; or (4) is likely to be a material witness in the case; or
- g.* Has any other legally sufficient cause to withdraw from participation in the decision making in that case.

10.20(2) The term “personally investigated” means taking affirmative steps to interview witnesses directly or to obtain documents or other information directly. The term “personally investigated” does not include general direction and supervision of assigned investigators, unsolicited receipt of information which is relayed to assigned investigators, review of another person’s investigative work product in the course of determining whether there is probable cause to initiate a proceeding or exposure to factual information while performing other agency functions, including fact gathering for purposes other than investigation of the matter which culminates in a contested case. Factual information relevant to the merits of a contested case received by a person who later serves as presiding officer in that case shall be disclosed if required by Iowa Code section 17A.17(3) and subrules 10.20(3) and 10.32(9).

10.20(3) In a situation where a presiding officer or other person knows of information which might reasonably be deemed to be a basis for disqualification and decides voluntary withdrawal is unnecessary, that person shall submit the relevant information for the record by affidavit and shall provide for the record a statement of the reasons for the determination that withdrawal is unnecessary.

10.20(4) If a party asserts disqualification on any appropriate ground, including those listed in subrule 10.20(1), the party shall file a motion supported by an affidavit pursuant to Iowa Code section 17A.17(7). The motion must be filed as soon as practicable after the reason alleged in the motion becomes known to the party. If, during the course of the hearing, a party first becomes aware of evidence of bias or other grounds for disqualification, the party may move for disqualification but must establish the grounds by the introduction of evidence into the record.

If the presiding officer determines that disqualification is appropriate, the presiding officer or other person shall withdraw. If the presiding officer determines that withdrawal is not required, the presiding

officer shall enter an order to that effect. A party asserting disqualification may seek an interlocutory appeal under rule 10.34(17A).

811—10.21(17A) Consolidation—severance.

10.21(1) Consolidation. The presiding officer may consolidate any or all matters at issue in two or more contested case proceedings where: (a) the matters at issue involve common parties or common questions of fact or law; (b) consolidation would expedite and simplify consideration of the issues involved; and (c) consolidation would not adversely affect the rights of any of the parties to those proceedings.

10.21(2) Severance. The presiding officer may, for good cause shown, order any contested case proceedings or portions thereof severed.

811—10.22(17A) Pleadings.

10.22(1) Pleadings may be required by rule, by notice of hearing, or by order of the presiding officer.

10.22(2) Petition.

a. Any petition required in a contested case proceeding shall be filed within 20 days of delivery or the notice of hearing or subsequent order of the presiding officer, unless otherwise ordered.

b. A petition shall state in separately numbered paragraphs the following:

- (1) The persons or entities on whose behalf the petition is filed;
- (2) The particular provision of statutes and rules involved;
- (3) The relief demanded and the facts and laws relied upon for such relief; and
- (4) The name, address and telephone number of the petitioner and the petitioner's attorney.

10.22(3) Answer. An answer may be filed within 20 days of service of the petition. A party may move to dismiss or apply for a more definite and detailed statement when appropriate.

An answer shall show on whose behalf it is filed and specifically admit, deny, or otherwise answer all material allegations of the pleading to which it responds. It shall state any facts deemed to show an affirmative defense and contain as many additional defenses as the pleader may claim.

An answer shall state the name, address and telephone number of the person filing the answer, the person or entity on whose behalf it is filed, and the attorney representing that person.

Any allegation in the petition not denied in the answer is considered admitted. The presiding officer may refuse to consider any defense not raised in the answer which could have been raised on the basis of facts known when the answer was filed if any party would be prejudiced.

811—10.23(17A) Service and filing of pleadings and other papers.

10.23(1) When service required. Except where otherwise provided by law, every pleading, motion, document, or other paper filed in a contested case proceeding and every paper relating to discovery in such a proceeding shall be served upon each of the parties of record to the proceeding, including the person designated as advocate or prosecutor for the state or the agency. Except for the original notice of hearing and an application for rehearing as provided in Iowa Code section 17A.16(2), the party filing a document is responsible for service on all parties.

10.23(2) Service—how made. Service upon a party represented by an attorney shall be made upon the attorney unless otherwise ordered. Service is made by delivery or by mailing a copy to the person's last-known address. Service by mail is complete upon mailing, except where otherwise specifically provided by statute, rule, or order.

10.23(3) Filing—when required. After the notice of hearing, all pleadings, motions, documents or other papers in a contested case proceeding shall be filed with the board.

10.23(4) Filing—when made. Except where otherwise provided by law, a document is deemed filed at the time it is delivered to the board office, delivered to an established courier service for immediate delivery to that office, or mailed by first-class mail or state interoffice mail to that office, so long as there is proof of mailing.

10.23(5) Proof of mailing. Proof of mailing includes either: a legible United States Postal Service postmark on the envelope, a certificate of service, a notarized affidavit, or a certification in substantially the following form:

I certify under penalty of perjury and pursuant to the laws of Iowa that, on (date of mailing), I mailed copies of (describe document) addressed to the (agency office and address) and to the names and addresses of the parties listed below by depositing the same in the United States mail or state interoffice mail.

(Date)

(Signature)

811—10.24(17A) Discovery.

10.24(1) Discovery procedures applicable in civil actions are applicable in contested cases. Unless lengthened or shortened by these rules or by order of the presiding officer, time periods for compliance with discovery shall be as provided in the Iowa Rules of Civil Procedure.

10.24(2) Any motion relating to discovery shall allege that the moving party has previously made a good-faith attempt to resolve the discovery issues involved with the opposing party. Motions in regard to discovery shall be ruled upon by the presiding officer. Opposing parties shall be afforded the opportunity to respond within ten days of the filing of the motion unless the time is shortened as provided in subrule 10.24(1). The presiding officer may rule on the basis of the written motion and any response, or may order argument on the motion.

10.24(3) Evidence obtained in discovery may be used in the contested case proceeding if that evidence would otherwise be admissible in that proceeding.

811—10.25(17A) Subpoenas.

10.25(1) Issuance.

a. An agency subpoena shall be issued to a party on request. Such a request must be in writing. In the absence of good cause for permitting later action, a request for a subpoena must be received at least three days before the scheduled hearing. The request shall include the name, address, and telephone number of the requesting party.

b. Except to the extent otherwise provided by law, parties are responsible for service of their own subpoenas and payment of witness fees and mileage expenses.

10.25(2) Motion to quash or modify. The presiding officer may quash or modify a subpoena for any lawful reason upon motion in accordance with the Iowa Rules of Civil Procedure. A motion to quash or modify a subpoena shall be set for argument promptly.

811—10.26(17A) Motions.

10.26(1) No technical form for motions is required. However, prehearing motions must be in writing, state the grounds for relief, and state the relief sought.

10.26(2) Any party may file a written response to a motion within ten days after the motion is served, unless the time period is extended or shortened by rules of the agency or the presiding officer. The presiding officer may consider a failure to respond within the required time period in ruling on a motion.

10.26(3) The presiding officer may schedule oral argument on any motion.

10.26(4) Motions pertaining to the hearing must be filed and served at least ten days prior to the date of hearing unless there is good cause for permitting later action or the time for such action is lengthened or shortened by rule of the agency or an order of the presiding officer.

811—10.27(17A) Prehearing conference.

10.27(1) Any party may request a prehearing conference. A written request for prehearing conference or an order for prehearing conference on the presiding officer's own motion shall be filed not less than seven days prior to the hearing date. A prehearing conference shall be scheduled not less than three business days prior to the hearing date.

Written notice of the prehearing conference shall be given by the board office to all parties. For good cause the presiding officer may permit variances from this rule.

10.27(2) Each party shall bring to the prehearing conference:

- a.* A final list of witnesses the party anticipates will testify at hearing. Witnesses not listed may be excluded from testifying unless there was good cause for the failure to include their names; and
- b.* A final list of exhibits which the party anticipates will be introduced at hearing. Exhibits other than rebuttal exhibits that are not listed may be excluded from admission into evidence unless there was good cause for the failure to include them.
- c.* Witness or exhibit lists may be amended subsequent to the prehearing conference within the time limits established by the presiding officer at the prehearing conference. Any such amendments must be served on all parties.

10.27(3) In addition to the requirements of subrule 10.27(2), the parties at a prehearing conference may:

- a.* Enter into stipulations of law or fact;
- b.* Enter into stipulations on the admissibility of exhibits;
- c.* Identify matters which the parties intend to request be officially noticed;
- d.* Enter into stipulations for waiver of any provision of law; and
- e.* Consider any additional matters which will expedite the hearing.

10.27(4) Prehearing conferences shall be conducted by telephone unless otherwise ordered. Parties shall exchange and receive witness and exhibit lists in advance of a telephone prehearing conference.

811—10.28(17A) Continuances. The executive secretary shall have the authority to grant a continuance after consultation, if needed, with the chairperson of the board.

A request for continuance of a contested case matter must be submitted in writing to the board not later than seven days prior to the scheduled date of the hearing. Exceptions shall be granted at the discretion of the executive secretary only in situations involving extenuating, extraordinary, or emergency circumstances.

811—10.29(17A) Hearing procedures.

10.29(1) The presiding officer presides at the hearing, and may rule on motions, require briefs, issue a decision, and issue such orders and rulings as will ensure the orderly conduct of the proceedings.

10.29(2) All objections shall be timely made and stated on the record.

10.29(3) Parties have the right to participate or be represented in all hearings or prehearing conferences related to their case. Any party may be represented by an attorney or another person authorized by law.

10.29(4) Subject to terms and conditions prescribed by the presiding officer, parties have the right to introduce evidence on issues of material fact, cross-examine witnesses present at the hearing as necessary for a full and true disclosure of the facts, present evidence in rebuttal, and submit briefs and engage in oral argument.

10.29(5) The presiding officer shall maintain the decorum of the hearing and may refuse to admit or may expel anyone whose conduct is disorderly.

10.29(6) Witnesses may be sequestered during the hearing.

10.29(7) The presiding officer shall conduct the hearing in the following manner:

- a.* The presiding officer shall give an opening statement briefly describing the nature of the proceedings;
- b.* The parties shall be given an opportunity to present opening statements;
- c.* Parties shall present their cases in the sequence determined by the presiding officer;
- d.* Each witness shall be sworn or affirmed by the presiding officer or the court reporter, and be subject to examination and cross-examination. The presiding officer may limit questioning in a manner consistent with law;
- e.* When all parties and witnesses have been heard, parties may be given the opportunity to present final arguments.

811—10.30(17A) Evidence.

10.30(1) The presiding officer shall rule on admissibility of evidence and may, where appropriate, take official notice of facts in accordance with all applicable requirements of law.

10.30(2) Stipulation of facts is encouraged. The presiding officer may make a decision based on stipulated facts.

10.30(3) Evidence in the proceeding shall be confined to those issues to which the parties received notice prior to the hearing, unless the parties waive their right to such notice or the presiding officer determines that good cause justifies expansion of the issues. If the presiding officer decides to admit evidence on issues outside the scope of the notice over the objection of a party who did not have actual notice of those issues, that party, upon timely request, shall receive a continuance sufficient to amend pleadings and to prepare on the additional issue.

10.30(4) The party seeking admission of an exhibit must provide opposing parties with an opportunity to examine the exhibit prior to the ruling on its admissibility. Copies of documents should normally be provided to opposing parties.

10.30(5) Any party may object to specific evidence or may request limits on scope of any examination or cross-examination. Such an objection shall be accompanied by a brief statement of the grounds upon which it is based. The objection, the ruling on the objection, and the reasons for the ruling shall be noted in the record. The presiding officer may rule on the objection at the time it is made or may reserve a ruling until the written decision.

10.30(6) Whenever evidence is ruled inadmissible, the party offering that evidence may submit an offer of proof on the record. The party making the offer of proof for excluded oral testimony shall briefly summarize the testimony or, with permission of the presiding officer, present the testimony. If the excluded evidence consists of a document or exhibit, it shall be marked as part of an order of proof and inserted in the record.

811—10.31(17A) Default.

10.31(1) If a party fails to appear or participate in a contested case proceeding after proper service of notice, the presiding officer may, if no adjournment is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party.

10.31(2) Where appropriate and not contrary to law, any party may move for default against a party who has requested the contested case proceeding and has failed to file a required pleading or has failed to appear after proper service.

10.31(3) Default decisions or decisions rendered on the merits after a party has failed to appear or participate in a contested case proceeding become final agency action unless, within 15 days after the date of notification or mailing of the decision, a motion to vacate is filed and served on all parties or an appeal of a decision on the merits is timely initiated within the time provided by rule 10.36(17A). A motion to vacate must state all facts relied upon by the moving party which establish that good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated must be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact attached to the motion.

10.31(4) The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate.

10.31(5) Properly substantiated and timely filed motions to vacate shall be granted only for good cause shown. The burden of proof as to good cause is on the moving party. Adverse parties shall have ten days to respond to a motion to vacate. Adverse parties shall be allowed to conduct discovery as to the issue of good cause and to present evidence on the issue prior to a decision on the motion, if a request to do so is included in that party's response.

10.31(6) "Good cause" for purposes of this rule shall have the same meaning as "good cause" for setting aside a default judgment under Iowa Rule of Civil Procedure 236.

10.31(7) A decision denying a motion to vacate is subject to further appeal within the time limit allowed for further appeal of a decision on the merits in the contested case proceeding. A decision

granting a motion to vacate is subject to interlocutory appeal by the adverse party pursuant to rule 10.34(17A).

811—10.32(17A) Ex parte communication.

10.32(1) Prohibited communications. Unless required for the disposition of ex parte matters specifically authorized by statute, following issuance of the notice of hearing, there shall be no communication, directly or indirectly, between the presiding officer and any party or representative of any party or any other person with a direct or indirect interest in such case in connection with any issue of fact or law in the case, except upon notice and opportunity for all parties to participate. This does not prohibit persons jointly assigned such tasks from communicating with each other. Nothing in this provision is intended to preclude the presiding officer from communicating with members of the agency or seeking the advice or help of persons other than those with a personal interest in, or those engaged in personally investigating as defined in subrule 10.20(2), prosecuting, or advocating in, either the case under consideration or a pending factually related case involving the same parties, as long as those persons do not directly or indirectly communicate to the presiding officer any ex parte communications they have received of a type that the presiding officer would be prohibited from receiving or that furnish, augment, diminish, or modify the evidence in the record.

10.32(2) Prohibitions on ex parte communications commence with the issuance of the notice of hearing in a contested case and continue for as long as the case is pending.

10.32(3) Written, oral or other forms of communication are “ex parte” if made without notice and opportunity for all parties to participate.

10.32(4) To avoid prohibited ex parte communications notice must be given in a manner reasonably calculated to give all parties a fair opportunity to participate. Notice of written communications shall be provided in compliance with rule 10.23(17A) and may be supplemented by telephone, facsimile, E-mail or other means of notification. Where permitted, oral communications may be initiated through telephone conference call, which includes all parties or their representatives.

10.32(5) Persons who jointly act as presiding officer in a pending contested case may communicate with each other without notice or opportunity for parties to participate.

10.32(6) The executive secretary or other persons may be present in deliberations or otherwise advise the presiding officer without notice or opportunity for parties to participate as long as they are not disqualified from participating in the making of a proposed or final decision under subrule 10.20(1) or other law and they comply with subrule 10.32(1).

10.32(7) Communications with the presiding officer involving scheduling or uncontested procedural matters do not require notice or opportunity for parties to participate. A party should notify other parties prior to initiating such contact with the presiding officer when feasible, and shall notify other parties when seeking to continue hearings or other deadlines pursuant to rule 10.29(17A).

10.32(8) Disclosure of prohibited communications. A presiding officer who received a prohibited ex parte communication during the pendency of a contested case must initially determine if the effect of the communication is so prejudicial that the presiding officer should be disqualified. If the presiding officer determines that disqualification is warranted, a copy of any prohibited written communication, all written responses to the communication, a written summary stating the substance of any prohibited oral or other communication not available in written form for disclosure, all responses made, and the identity of each person from whom the presiding officer received a prohibited ex parte communication shall be submitted for inclusion in the record under seal by protective order. If the presiding officer determines that disqualification is not warranted, such documents shall be submitted for inclusion in the record and served on all parties. Any party desiring to rebut the prohibited communication must be allowed the opportunity to do so upon written request filed within ten days after notice of the communication.

10.32(9) Promptly after being assigned to serve as presiding officer on a hearing panel, as a member of a full board hearing, on an intra-agency appeal, or other basis, a presiding officer shall disclose to all parties material factual information received through ex parte communication prior to such assignment, unless the factual information has already been or shortly will be disclosed pursuant to Iowa Code section 17A.13(2) or through discovery. Factual information contained in an investigative report or similar

document need not be separately disclosed by the presiding officer as long as such documents have been or will shortly be provided to the parties.

10.32(10) The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule including default, a decision against the offending party, censure, or suspension or revocation of the privilege to practice before the agency. Violation of ex parte communication prohibitions by agency personnel shall be reported to the board's executive secretary for possible sanctions including: censure, suspension, dismissal, or other disciplinary action.

811—10.33(17A) Recording costs. Upon request, the board shall provide a copy of the whole or any portion of the record at cost. The cost of preparing a copy of the record or of transcribing the hearing record shall be paid by the requesting party.

Parties who request that a hearing be recorded by certified shorthand reporters rather than by electronic means shall bear the cost of such recording, unless otherwise provided by law.

811—10.34(17A) Final decision. When the board presides over reception of the evidence at the hearing, its decision is a final decision.

10.34(1) When a panel of specialists presides over the reception of evidence at the hearing, the findings of fact shall be considered by the board at the earliest feasible time. The decision of the board is a final decision.

10.34(2) A final decision in a contested case proceeding shall be in writing and include findings of fact and conclusions of law, separately stated.

a. Findings of fact shall be accompanied by a concise and explicit statement of underlying facts supporting the findings.

b. The decision shall include an explanation of why the relevant evidence in the record supports each material finding of fact.

c. Conclusions of law shall be supported by cited authority or by a reasoned opinion.

10.34(3) The decision or order shall be promptly delivered to the parties in the manner provided by Iowa Code section 17A.12.

10.34(4) The final decision is a public record pursuant to Iowa Code section 272C.6(4).

811—10.35(17A) Appeals.

10.35(1) Appeal by party. Any adversely affected party may appeal a final decision of the board to the district court within 30 days after issuance, in accordance with Iowa Code section 17A.19.

10.35(2) Review. The board may initiate review of the decision or order on its own motion at any time within 30 days following the issuance of such a decision.

10.35(3) Notice of appeal. An appeal of a decision or order is initiated by filing a timely notice of appeal with the board. The notice of appeal must be signed by the appealing party or a representative of that party and contain a certificate of service. The notice shall specify:

a. The parties initiating the appeal;

b. The proposed decision or order appealed from;

c. The specific findings or conclusions to which exception is taken and any other exceptions to the decision or order;

d. The relief sought;

e. The grounds for relief.

10.35(4) Requests to present additional evidence. A party may request the taking of additional evidence only by establishing that the evidence is material, that good cause existed for the failure to present the evidence at the hearing, and that the party has not waived the right to present the evidence. A written request to present additional evidence must be filed with the notice of appeal or, by a nonappealing party, within 15 days of service of the notice of appeal. The board may remand a case to the presiding officer for further hearing or may itself preside at the taking of additional evidence.

10.35(5) Scheduling. The board of veterinary medicine shall issue a schedule for consideration of the appeal.

10.35(6) Briefs and arguments. Unless otherwise ordered, within 20 days of the notice of appeal or order for review, each appealing party may file exceptions and briefs. Within 20 days thereafter, any party may file a responsive brief. Briefs shall cite any applicable legal authority and specify relevant portions of the record in that proceeding. Written requests to present an oral argument shall be filed with the briefs.

The board may resolve the appeal on the briefs or provide an opportunity for oral argument. The board may shorten or extend the briefing period as appropriate.

811—10.36(17A) Applications for rehearing.

10.36(1) By whom filed. Any party to a contested case proceeding may file an application for rehearing from a final order.

10.36(2) Content of application. The application for rehearing shall state on whose behalf it is filed, the specific grounds for rehearing, and the relief sought. In addition, the application shall state whether the applicant desires reconsideration of all or part of the agency decision on the existing record and whether, on the basis of the grounds enumerated in subrule 10.36(4), the applicant requests an opportunity to submit additional evidence.

10.36(3) Time of filing. The application shall be filed with the board office within 20 days after issuance of the final decision.

10.36(4) Notice to other parties. A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein. If the application does not contain a certificate of service, the board shall serve copies on all parties.

10.36(5) Disposition. Any application for a rehearing shall be deemed denied unless the agency grants the application within 20 days after its filing.

811—10.37(17A) No factual dispute contested cases. If the parties agree that no dispute of material fact exists as to a matter that would be a contested case if such a dispute of fact existed, the parties may present all relevant admissible evidence either by stipulation or otherwise as agreed by the parties, without necessity for the production of evidence at an evidentiary hearing. If such agreement is reached, a jointly submitted schedule detailing the method and timetable for submission of the record, briefs and oral argument should be submitted to the presiding officer for approval as soon as practicable.

811—10.38(17A) Emergency adjudicative proceedings.

10.38(1) Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, the board may issue a written order in compliance with Iowa Code section 17A.18 to suspend a credential in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the board by emergency adjudicative order. Before issuing an emergency adjudicative order, the board shall consider factors including, but not limited to, the following:

- a. Whether there has been a sufficient factual investigation to ensure that the board is proceeding on the basis of reliable information;
- b. Whether the specific circumstances which pose immediate danger to the public health, safety, or welfare have been identified and determined to be continuing;
- c. Whether the person required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety, or welfare;
- d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and
- e. Whether the specific action contemplated by the board is necessary to avoid the immediate danger.

10.38(2) Issuance. The written emergency adjudicative order shall be immediately delivered to persons who are required to comply with the order by utilizing one or more of the following procedures:

- a. Personal delivery;
- b. Certified mail, return receipt requested, to the last address on file with the board;

- c. Certified mail to the last address on file with the board;
- d. First-class mail to the last address on file with the board; or
- e. Fax. Fax may be used as the sole method of delivery if the person required to comply with the order has filed a written request that board orders be sent by fax and has provided a fax number for that purpose.

To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

10.38(3) Oral notice. Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the board shall make reasonable immediate efforts to contact by telephone the persons who are required to comply with the order.

10.38(4) Completion of proceedings. Issuance of a written emergency adjudicative order shall include notification of the date on which board proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further board proceedings to a later date will be granted only in compelling circumstances upon application in writing.

811—10.39(272C) Disciplinary hearing—fees and costs.

10.39(1) Definitions. As used in this rule in relation to a formal disciplinary action filed by the board against a credential holder:

“*Deposition*” means the testimony of a person taken pursuant to subpoena or at the request of the state of Iowa taken in a setting other than a hearing.

“*Expenses*” means costs incurred by persons appearing pursuant to subpoena or at the request of the state of Iowa for purposes of providing testimony on the part of the state of Iowa in a hearing or other official proceeding and shall include mileage reimbursement at the rate specified in Iowa Code section 70A.9 or, if commercial air or ground transportation is used, the actual cost of transportation to and from the proceeding. Also included are actual costs incurred for meals and necessary lodging.

“*Medical examination fees*” means actual costs incurred by the board in a physical, mental, chemical abuse, or other impairment-related examination or evaluation of a credential holder when the examination or evaluation is conducted pursuant to an order of the board.

“*Record*” means the proceedings of the hearing including, but not limited to, the transcript and any documentary evidence admitted or offered at the hearing.

“*Transcript*” means a printed verbatim reproduction of everything said on the record during a hearing or other official proceeding.

“*Witness fees*” means compensation paid by the board to persons appearing pursuant to subpoena or at the request of the state of Iowa for purposes of providing testimony on the part of the state of Iowa. For the purpose of this rule, compensation shall be the same as outlined in Iowa Code section 622.69 or 622.72, as applicable.

10.39(2) Disciplinary hearing fee. The board may charge a fee not to exceed the amount authorized in Iowa Code section 272C.6 for conducting a disciplinary hearing which results in disciplinary action taken against the credential holder by the board. An order assessing a fee shall be included as part of the board’s final decision. The order shall direct the credential holder to deliver payment directly to the department of agriculture and land stewardship as provided in subrule 10.39(6).

10.39(3) Recovery of related hearing costs. The board may also recover from the credential holder the costs for transcripts, witness fees and expenses, depositions, and medical examination fees, if disciplinary action is taken. The board may assess these costs in the manner it deems most equitable in accordance with the following:

a. *Transcript costs.* The board may assess the transcript costs against the credential holder pursuant to Iowa Code section 272C.6(6) or against the requesting party pursuant to Iowa Code section 17A.12(7).

(1) The cost of the transcript includes the transcript of the original contested case hearing before the board, as well as transcripts of any other formal proceedings before the board which occur after the notice of the contested case hearing is filed.

(2) In the event of an appeal to the full board from a proposed decision, the appealing party shall timely request and pay for the transcript necessary for use in the board appeal process.

b. Witness fees and expenses. The parties in a contested case shall be responsible for any witness fees and expenses incurred by witnesses appearing at the contested case hearing. In addition, the board may assess a credential holder the witness fees and expenses incurred by witnesses called to testify on behalf of the state of Iowa, provided that the costs are calculated as follows:

(1) The costs for lay witnesses shall be determined in accordance with Iowa Code section 622.69. For purposes of calculating the mileage expenses allowed under that section, the provisions of Iowa Code section 625.2 do not apply.

(2) The costs for expert witnesses shall be determined in accordance with Iowa Code section 622.72. For purposes of calculating the mileage expenses allowed under that section, the provisions of Iowa Code section 625.2 do not apply.

(3) The provisions of Iowa Code section 622.74 regarding advance payment of witness fees and the consequences of failure to make such payment are applicable with regard to witnesses who are subpoenaed by either party to testify at the hearing.

(4) The board may assess as costs the meal and lodging expenses necessarily incurred by witnesses testifying at the request of the state of Iowa. Meal and lodging costs shall not exceed the reimbursement employees of the state of Iowa receive for these expenses under the department of revenue guidelines currently in effect.

c. Deposition costs. Deposition costs for purposes of allocating costs against a credential holder include only those deposition costs incurred by the state of Iowa. The credential holder is directly responsible for the payment of deposition costs incurred by the credential holder.

(1) The costs for depositions include the cost of transcripts, the daily charge of the court reporter for attending and transcribing the deposition, and all mileage and travel time charges of the court reporter for traveling to and from the deposition which are charged in the ordinary course of business.

(2) If the deposition is of an expert witness, the deposition costs include a reasonable fee for an expert witness. This fee shall not exceed the expert's customary hourly or daily fee, and shall include the time reasonably and necessarily spent in connection with the deposition, including the time spent in travel to and from the deposition, but excluding time spent in preparation for the deposition.

d. Medical examination fees. All costs of physical or mental examinations ordered by the board pursuant to Iowa Code section 272C.9(1) as part of an investigation of a pending complaint or as a sanction following a contested case shall be paid directly by the credential holder.

10.39(4) Certification of reimbursable costs. Within ten days after conclusion of a contested case hearing and before issuance of any final decision assessing costs, the secretary shall certify any reimbursable costs to the board. The secretary shall calculate the specific costs, certify the costs calculated, and file the certification as part of the record in the contested case. A copy of the certification shall be served on each party of record at the time of the filing.

10.39(5) Assessment of fees and costs. A final decision of the board imposing disciplinary action against a credential holder shall include the amount of any fee assessed. If the board also assesses costs against the credential holder, the final decision shall include a statement of costs delineating each category of costs and the amount assessed. The board shall specify the time period in which the fees and costs must be paid by the credential holder.

a. A party shall file an objection to any fees or costs imposed in a final decision in order to exhaust administrative remedies. An objection shall be filed in the form of an application for rehearing pursuant to Iowa Code section 17A.16(2).

b. The application shall be resolved by the board consistent with the procedures for ruling on an application for rehearing. Any dispute regarding the calculations of any fees or costs to be assessed may be resolved by the board upon receipt of the parties' written objections.

10.39(6) Payment of fees and costs. Payment for fees and costs assessed pursuant to this rule shall be made in the form of a check or money order made payable to the state of Iowa and delivered by the credential holder to the department of agriculture and land stewardship.

10.39(7) *Failure to make payment.* Failure of a credential holder to pay any fees and costs within the time specified in the board's decision shall constitute a violation of an order of the board and shall constitute grounds for disciplinary action.

These rules are intended to implement Iowa Code chapters 17A, 169, and 272C.

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