IOWA ADMINISTRATIVE BULLETIN

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June 17, 2020 Pages 2745 to 2840

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PREFACE

The Iowa Administrative Bulletin is published biweekly pursuant to Iowa Code chapters 2B and 17A and contains Notices of Intended Action and rules adopted by state agencies.

It also contains Proclamations and Executive Orders of the Governor which are general and permanent in nature; Regulatory Analyses; effective date delays and objections filed by the Administrative Rules Review Committee; Agenda for monthly Administrative Rules Review Committee meetings; and other materials deemed fitting and proper by the Administrative Rules Review Committee.

The Bulletin may also contain public funds interest rates [12C.6]; usury rates [535.2(3)"a"]; agricultural credit corporation maximum loan rates [535.12]; and other items required by statute to be published in the Bulletin.

PLEASE NOTE: Underscore indicates new material added to existing rules; ~~strike through~~ indicates deleted material.

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CITATION of Administrative Rules

The Iowa Administrative Code shall be cited as (agency identification number) IAC (chapter, rule, subrule, paragraph, subparagraph, or numbered paragraph).

This citation format applies only to external citations to the Iowa Administrative Code or Iowa Administrative Bulletin and does not apply to citations within the Iowa Administrative Code or Iowa Administrative Bulletin.

441 IAC 79	(Chapter)
441 IAC 79.1	(Rule)
441 IAC 79.1(1)	(Subrule)
441 IAC 79.1(1)"a"	(Paragraph)
441 IAC 79.1(1)"a"(1)	(Subparagraph)
441 IAC 79.1(1)"a"(1)"1"	(Numbered paragraph)

The Iowa Administrative Bulletin shall be cited as IAB (volume), (number), (publication date), (page number), (ARC number).

IAB Vol. XII, No. 23 (5/16/90) p. 2050, ARC 872A

NOTE: In accordance with Iowa Code section 2B.5A, a rule number within the Iowa Administrative Code includes a reference to the statute which the rule is intended to implement: 441—79.1(249A).

Schedule for Rule Making
2020

NOTICE† SUBMISSION DEADLINE	NOTICE PUB. DATE	HEARING OR COMMENTS 20 DAYS	FIRST POSSIBLE ADOPTION DATE 35 DAYS	ADOPTED FILING DEADLINE	ADOPTED PUB. DATE	FIRST POSSIBLE EFFECTIVE DATE	POSSIBLE EXPIRATION OF NOTICE 180 DAYS
Dec. 26 '19	Jan. 15 '20	Feb. 4 '20	Feb. 19 '20	Feb. 21 '20	Mar. 11 '20	Apr. 15 '20	July 13 '20
Jan. 8	Jan. 29	Feb. 18	Mar. 4	Mar. 6	Mar. 25	Apr. 29	July 27
Jan. 24	Feb. 12	Mar. 3	Mar. 18	Mar. 20	Apr. 8	May 13	Aug. 10
Feb. 7	Feb. 26	Mar. 17	Apr. 1	Apr. 3	Apr. 22	May 27	Aug. 24
Feb. 21	Mar. 11	Mar. 31	Apr. 15	Apr. 17	May 6	June 10	Sep. 7
Mar. 6	Mar. 25	Apr. 14	Apr. 29	May 1	May 20	June 24	Sep. 21
Mar. 20	Apr. 8	Apr. 28	May 13	**May 13**	June 3	July 8	Oct. 5
Apr. 3	Apr. 22	May 12	May 27	May 29	June 17	July 22	Oct. 19
Apr. 17	May 6	May 26	June 10	June 12	July 1	Aug. 5	Nov. 2
May 1	May 20	June 9	June 24	**June 24**	July 15	Aug. 19	Nov. 16
May 13	June 3	June 23	July 8	July 10	July 29	Sep. 2	Nov. 30
May 29	June 17	July 7	July 22	July 24	Aug. 12	Sep. 16	Dec. 14
June 12	July 1	July 21	Aug. 5	Aug. 7	Aug. 26	Sep. 30	Dec. 28
June 24	July 15	Aug. 4	Aug. 19	**Aug. 19**	Sep. 9	Oct. 14	Jan. 11 '21
July 10	July 29	Aug. 18	Sep. 2	Sep. 4	Sep. 23	Oct. 28	Jan. 25 '21
July 24	Aug. 12	Sep. 1	Sep. 16	Sep. 18	Oct. 7	Nov. 11	Feb. 8 '21
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Sep. 4	Sep. 23	Oct. 13	Oct. 28	**Oct. 28**	Nov. 18	Dec. 23	Mar. 22 '21
Sep. 18	Oct. 7	Oct. 27	Nov. 11	**Nov. 12**	Dec. 2	Jan. 6 '21	Apr. 5 '21
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Oct. 16	Nov. 4	Nov. 24	Dec. 9	**Dec. 9**	Dec. 30	Feb. 3 '21	May 3 '21
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PRINTING SCHEDULE FOR IAB

ISSUE NUMBER	SUBMISSION DEADLINE	ISSUE DATE
2	**Wednesday, June 24, 2020**	**July 15, 2020**
3	**Friday, July 10, 2020**	**July 29, 2020**
4	**Friday, July 24, 2020**	**August 12, 2020**

PLEASE NOTE:

Rules will not be accepted by the Publications Editing Office after **12 o'clock noon** on the filing deadline unless prior approval has been received from the Administrative Rules Coordinator and the Administrative Code Editor.

If the filing deadline falls on a legal holiday, submissions made on the following Monday will be accepted.

†To allow time for review by the Administrative Rules Coordinator prior to the Notice submission deadline, Notices should generally be submitted in RMS four or more working days in advance of the deadline.

****Note change of filing deadline****

NOTE: See also the Advisory Notice on page 2838.

ENVIRONMENTAL PROTECTION COMMISSION[567]

Aquatic life water quality criteria for certain metals, 61.3(3) IAB 6/3/20 **ARC 5044C**	Via video/conference call Contact Roger Bruner Email: roger.bruner@dnr.iowa.gov	June 23, 2020 3 to 4 p.m.

PROFESSIONAL LICENSURE DIVISION[645]

Physician assistants—licensure, practice, discipline, 326.1, 326.6, 326.15, 326.18, 326.19(3)"b," 327.1, 327.4, 327.5, 327.6(2), 329.2(25) IAB 6/3/20 **ARC 5043C**	Fifth Floor Conference Room 526 Lucas State Office Bldg. Des Moines, Iowa	June 23, 2020 8 to 8:30 a.m.

The following list will be updated as changes occur.

"Umbrella" agencies and elected officials are set out below at the left-hand margin in CAPITAL letters.

Divisions (boards, commissions, etc.) are indented and set out in lowercase type under their statutory "umbrellas."

Other autonomous agencies are included alphabetically in SMALL CAPITALS at the left-hand margin.

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ADMINISTRATIVE SERVICES DEPARTMENT

Public Notice

NOTICE OF OFFICIAL PUBLICATION RATE INCREASE FOR THE FISCAL YEAR COMMENCING JULY 1, 2020, AND ENDING JUNE 30, 2021

In accordance with Iowa Code section 618.11, the Iowa Department of Administrative Services Director hereby publishes the lineage rate* for newspaper publications of any order, citation, or other publication required or allowed by law (also known as official publications) for the period commencing on July 1, 2020, and ending on June 30, 2021, in the following amounts:

* Lineage rate: "…each line of eight point type two inches in length, or its equivalent." (Iowa Code section 618.11)

One insertion = 50.3 cents
Each subsequent insertion = 33.9 cents

The rate becomes effective on July 1, 2020. The rate was determined by applying the formula specified in the statute. According to the federal Department of Labor, Bureau of Labor Statistics, the consumer price index for all urban consumers increased 0.3% for the 12 months ended April 2020. The April index was the most recent index available as of May 19, 2020, the date on which this notice was submitted for publication.

Pursuant to Iowa Code section 618.11, the calculation and publication of the rate by the Director of the Department of Administrative Services shall be exempt from the provisions of chapters 17A and 25B.

If you have questions regarding this notice, please contact:

Annette M. Dunn, Director
Office of the Chief Information Officer
200 E. Grand Ave.
Des Moines, Iowa 50319
Telephone: 515.281.3462
Email: annette.dunn@iowa.gov

ARC 5049C

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Proposing rule making related to MEPD program premium amounts and providing an opportunity for public comment

The Human Services Department hereby proposes to amend Chapter 75, "Conditions of Eligibility," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 249A.3.

HUMAN SERVICES DEPARTMENT[441](cont'd)

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 249A.3.

Purpose and Summary

This proposed amendment adjusts federal poverty level (FPL) increments used to assess premiums for applicants and recipients with income over 150 percent of the FPL under the Medicaid for Employed People with Disabilities (MEPD) program.

Iowa Code section 249A.3(2)"a"(1)(b) requires that the maximum premium payable by an individual whose income exceeds 150 percent of the official poverty guidelines shall be commensurate with the cost of state employees' group health insurance in this state. The average cost to the state for state employees' health insurance for a single person is $829 effective January 1, 2020. Therefore, the maximum premium cannot be above that amount.

The new premium scale updates the increase in the maximum premium allowed to reflect the increase in the cost of state employees' health insurance by adding an additional premium tier (1,550 percent of the FPL and above equals the $829 premium). All other amounts will be increased a small amount.

Fiscal Impact

The impact to members from the increase in premiums is expected to be minimal, so the savings to the State from the premium increase also would be minimal. Based on current members, the average monthly premium increase is expected to be approximately $1.20. With approximately 4,200 members paying premiums each month, this equates to an annual revenue increase of approximately $61,000 (total), of which $23,000 is the State share.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to rule 441—1.8(17A,217).

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on July 7, 2020. Comments should be directed to:

Nancy Freudenberg
Department of Human Services
Hoover State Office Building, Fifth Floor
1305 East Walnut Street
Des Moines, Iowa 50319-0114
Email: appeals@dhs.state.ia.us

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

HUMAN SERVICES DEPARTMENT[441](cont'd)

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend subparagraph **75.1(39)"b"(3)** as follows:

(3) Premiums shall be assessed as follows:

IF THE INCOME OF THE APPLICANT IS ABOVE:	THE MONTHLY PREMIUM IS:
150% of Federal Poverty Level	~~$34~~ $35
165% of Federal Poverty Level	~~$47~~ $48
180% of Federal Poverty Level	~~$56~~ $57
200% of Federal Poverty Level	~~$66~~ $67
225% of Federal Poverty Level	~~$77~~ $79
250% of Federal Poverty Level	~~$89~~ $92
300% of Federal Poverty Level	~~$112~~ $115
350% of Federal Poverty Level	~~$137~~ $140
400% of Federal Poverty Level	~~$161~~ $165
450% of Federal Poverty Level	~~$186~~ $190
550% of Federal Poverty Level	~~$232~~ $237
650% of Federal Poverty Level	~~$280~~ $286
750% of Federal Poverty Level	~~$329~~ $337
850% of Federal Poverty Level	~~$389~~ $398
1000% of Federal Poverty Level	~~$467~~ $477
1150% of Federal Poverty Level	~~$547~~ $559
1300% of Federal Poverty Level	~~$631~~ $644
1480% of Federal Poverty Level	~~$729~~ $744
1550% of Federal Poverty Level	$829

TREASURER OF STATE

Notice—Public Funds Interest Rates

In compliance with Iowa Code chapter 74A and section 12C.6, the committee composed of Treasurer of State Michael L. Fitzgerald, Superintendent of Credit Unions Katie Averill, Superintendent of Banking Jeff Plagge, and Auditor of State Rob Sand has established today the following rates of interest for public obligations and special assessments. The usury rate for June is 2.75%.

INTEREST RATES FOR PUBLIC OBLIGATIONS AND ASSESSMENTS

74A.2 Unpaid Warrants . . . . . Maximum 6.0%

74A.4 Special Assessments . . . . . Maximum 9.0%

TREASURER OF STATE(cont'd)

RECOMMENDED Rates for Public Obligations (74A.3) and School District Warrants (74A.7). A rate equal to 75% of the Federal Reserve monthly published indices for U.S. Government securities of comparable maturities. All Financial Institutions as defined by Iowa Code section 12C.1 are eligible for public fund deposits as defined by Iowa Code section 12C.6A.

The rate of interest has been determined by a committee of the state of Iowa to be the minimum interest rate that shall be paid on public funds deposited in approved financial institutions. To be eligible to accept deposits of public funds of the state of Iowa, a financial institution shall demonstrate a commitment to serve the needs of the local community in which it is chartered to do business. These needs include credit services as well as deposit services. All such financial institutions are required to provide the committee with a written description of their commitment to provide credit services in the community. This statement is available for examination by citizens.

New official state interest rates, effective June 9, 2020, setting the minimums that may be paid by Iowa depositories on public funds are listed below.

TIME DEPOSITS

7-31 days	Minimum .05%
32-89 days	Minimum .05%
90-179 days	Minimum .05%
180-364 days	Minimum .05%
One year to 397 days	Minimum .05%
More than 397 days	Minimum .10%

These are minimum rates only. All time deposits are four-tenths of a percent below average rates. Public body treasurers and their depositories may negotiate a higher rate according to money market rates and conditions.

Inquiries may be sent to Michael L. Fitzgerald, Treasurer of State, State Capitol, Des Moines, Iowa 50319.

ARC 5050C
AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21]

Adopted and Filed

Rule making related to hemp

The Agriculture and Land Stewardship Department hereby rescinds Chapter 96, "Hemp," Iowa Administrative Code and adopts a new Chapter 96 with the same title.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 204.3(5).

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 204.

Purpose and Summary

This rule making is in response to additional requirements requested by the United States Department of Agriculture (USDA) to ensure compliance with the Agriculture Improvement Act of 2018, which amended the Agricultural Marketing Act of 1946, and to ensure compliance with further restrictions found in 2019 Iowa Acts, Senate File 599.

Fulfillment of these changes is necessary for the Department to receive USDA approval of the state plan to administer an industrial hemp program.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 11, 2020, as **ARC 4988C**. This rule making was also adopted and filed emergency and published in the Iowa Administrative Bulletin as **ARC 4989C** on the same date. A public hearing was held on April 3, 2020, at 9 a.m. by telephone. No one attended the public hearing. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Department on May 28, 2020.

Fiscal Impact

2019 Iowa Acts, Senate File 599, increases expenditures for the Department by an estimated $304,000 in FY 2020 and $209,000 in FY 2021. The fee income that will be deposited into the hemp fund cannot be estimated, because it is unknown how many persons will participate in the manufacturing of industrial hemp.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 21—Chapter 8.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020, at which time the Adopted and Filed Emergency rule making is hereby rescinded.

The following rule-making action is adopted:

Rescind 21—Chapter 96 and adopt the following **new** chapter in lieu thereof:

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 indicia* 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.

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.

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.

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.

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.

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.

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 of 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.

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.

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.

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.

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.

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.

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.

These rules are intended to implement Iowa Code section 204.3.

[Filed 5/29/20, effective 7/22/20]
[Published 6/17/20]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5052C

ENVIRONMENTAL PROTECTION COMMISSION[567]

Adopted and Filed

Rule making related to water permitting

The Environmental Protection Commission (Commission) hereby rescinds Chapter 9, "Delegation of Construction Permitting Authority," adopts a new Chapter 9 with the same title, and amends Chapter 50, "Scope of Division—Definitions—Forms—Rules of Practice," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 455B.105, 455B.173 and 455B.265.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 17A.3, 455B.105, 455B.171, 455B.172, 455B.173 to 455B.176, 455B.177 to 455B.183, 455B.184 to 455B.187, 455B.261, 455B.262, 455B.264, 455B.265, 455B.266 to 455B.274 and 455B.278.

Purpose and Summary

This rule making conforms the rules with 2019 Iowa Acts, Senate File 409, signed by Governor Reynolds on May 9, 2019. Chapter 9 is rescinded and a new Chapter 9 is adopted which provides wastewater and water supply delegated construction permitting authority for wastewater sewer extensions and water supply water main extensions to rural water systems organized under Iowa Code chapter 357A or 504. Other rule making changes include updating forms, updating references to construction standards, and establishing criteria for rescission and revocation of delegated permitting authority.

Chapter 50 has two amendments. The first amendment changes the Iowa Department of Natural Resources' (Department's) annual permit fee budgeting criteria to evaluate expenses in past and succeeding years. The second amendment changes the requirement for a second public notice for water use permit issuance at community public water supplies, allowing for the use of alternate methods of publishing the notice.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4919C**. A public hearing was held on March 4, 2020, at 10 a.m. at the Wallace State Office Building, Des Moines, Iowa. No one attended the public hearing. No public comments were received prior to the close of the public comments. Comments in support of the rule making were received from the Iowa Rural Water Association after the close of the public comment period. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 19, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 561—Chapter 10.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Rescind 567—Chapter 9 and adopt the following **new** chapter in lieu thereof:

CHAPTER 9
DELEGATION OF CONSTRUCTION PERMITTING AUTHORITY

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.

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

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.

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.

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.

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).

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.

These rules are intended to implement Iowa Code sections 17A.3, 455B.105 and 455B.171 to 455B.187.

ITEM 2. Amend subparagraph **50.4(2)"b"(2)** as follows:

(2) The annual fee shall be based on the costs for administering the water use permitting program for the previous calendar ~~year~~ years and on the ~~budget~~ anticipated expenses for ~~the next~~ succeeding fiscal ~~year~~ 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.

ITEM 3. Amend paragraph **50.7(3)"a"** as follows:

a. New permits and modifications of permits.

~~(1) Applicable to all except community public water supplies. Before~~ 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 ~~shall~~ 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.

~~(2) Applicable only to community public water supplies. Prior to the issuance of a permit to withdraw, divert or inject water to a community public water supply, the department shall publish a notice of recommendation to grant a permit. 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 shall include a brief summary of the proposed permit and shall be published in a newspaper of general circulation within the county of the proposed water source as provided in Iowa Code section 618.3. If the newspaper of general circulation is not the newspaper of the nearest locality to the proposed water source that publishes a newspaper, the notice shall also be published in the newspaper of the nearest locality to the proposed water source that publishes a newspaper, and the department may charge the applicant for the expenses associated with publishing the notice in the second newspaper. The notice shall be sent to any person who has requested a copy of the notice concerning the particular water use under consideration.~~

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5051C

ENVIRONMENTAL PROTECTION COMMISSION[567]

Adopted and Filed

Rule making related to air quality

The Environmental Protection Commission (Commission) hereby amends Chapter 20, "Scope of Title—Definitions," Chapter 22, "Controlling Pollution," Chapter 23, "Emission Standards for Contaminants," Chapter 25, "Measurement of Emissions," Chapter 30, "Fees," and Chapter 33, "Special Regulations and Construction Permit Requirements for Major Stationary Sources—Prevention of Significant Deterioration (PSD) of Air Quality," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 455B.133 and 455B.134.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 455B.133 and 455B.134.

Purpose and Summary

The purposes of this rule making are to:

1. Reduce the cost of government while providing streamlined services to the public and the regulated community.

2. Update rules to provide regulatory certainty and flexibility. The amendments implement a portion of the five-year review of rules plan of the Department of Natural Resources (Department) pursuant to Iowa Code section 17A.7(2).

3. Offer uniform rules by making changes that match federal regulations and eliminate inconsistencies between federal regulations and state administrative rules. By adopting federal updates into state administrative rules, the Commission is ensuring that Iowa's air quality rules are no more stringent than the federal regulations. Additionally, the updates allow the Department, rather than the U.S. Environmental Protection Agency (EPA), to be the primary agency to implement the air quality requirements in Iowa, thereby allowing the Department to provide compliance assistance and outreach to affected facilities.

Item 1 amends rule 567—20.2(455B), the definition of "anaerobic lagoon," to further clarify that this definition is applicable to only the air quality requirements as specified in 567—Chapters 20 through 35. The Commission is clarifying the definition because other Department regulations, such as those for wastewater, may contain different meanings for the term "anaerobic lagoon" that are specific to permitting or other requirements for that particular environmental program area.

Item 1 also amends the definition of "EPA reference method" to adopt the most current EPA methods for measuring air pollutant emissions, performance testing (sometimes called "stack testing"), and continuous monitoring. On November 14, 2018, EPA revised the reference methods in 40 Code of Federal Regulations (CFR) Parts 51, 60, and 63 to eliminate outdated procedures, add alternative testing methods, make technical corrections, and correct typographical and grammatical errors. EPA states that its revisions will improve the quality of data and provide flexibility in the use of approved alternative procedures, while not imposing any new substantive requirements on source owners or operators.

The amendments in **Items 4, 8, 9,** and **11** are adopted concurrently with the amendment in Item 1 to similarly reflect updates to EPA testing and monitoring methods as the methods apply to specific air quality requirements. Item 4 updates the definition of "EPA reference method" for the Title V operating permit rules in 567—Chapter 22 in the same manner as the definition is amended in Item 1. Items 8 and 9 adopt by reference the federal updates into the regulations for New Source Performance Standards (NSPS) and National Emissions Standards for Hazardous Air Pollutants (NESHAP) in 567—Chapter 23, as explained below. Item 11 adopts the federal updates by reference into the performance testing and continuous monitoring requirements in 567—Chapter 25. Adopting EPA's updates ensures that state reference testing methods match current federal reference methods and are no more stringent than the federal methods.

Additionally, Item 1 updates the definition of "volatile organic compounds" (VOC) to reflect changes that EPA made to the federal definition of VOC. On November 28, 2018, a final regulation was published in the Federal Register to exclude the compound cis-1,1,1,4,4,4-hexafluorobut-2-ene (also known as HFO–1336mzz–Z) from the federal definition because this compound makes a negligible contribution to tropospheric ozone formation. In Item 13, an amendment to subrule 33.3(1) is adopted concurrently with the amendment in Item 1 to similarly update the definition of "volatile organic compounds" for the Prevention of Significant Deterioration (PSD) rules in 567—Chapter 33.

Items 2, 4, 5, 6, and **12** add new definitions for "electronic format," "electronic submittal," and "electronic submittal format" to facilitate the Department's launch of the Iowa Environmental Application System—EASY Air (EASY Air), a new online electronic method for submitting air quality permit applications. EASY Air is making application preparation easier, improving customer service, and expediting the Department's ability to issue permits while increasing data accuracy and cutting costs. Additionally, EASY Air allows online submittal of streamlined alternatives to traditional applications, such as registrations, notifications, and template applications. EASY Air launched for permit application submittal on December 5, 2019.

Items 3 and **7** amend rules to enable electronic submittal. Item 3 updates the construction permit application provisions to specify the types of submittals that may include an electronic submittal option. Item 7 revises the requirements for acid rain permit applications to specify that only one copy of an application is required to be submitted if paper forms are used or, alternatively, the application may be submitted through the electronic submittal method specified by the Department.

Items 8 and **9** adopt changes to the NSPS and NESHAP, respectively. The U.S. Clean Air Act (CAA) obligates EPA to issue standards to control air pollution. The NSPS and NESHAP set federal standards and deadlines for industrial, commercial or institutional facilities to meet uniform standards for equipment operation and air pollutant emissions.

NESHAP requirements differ depending on whether a facility is a "major source" or an "area source." Major sources are typically larger facilities and have potential emissions of 10 tons or more per year of any single hazardous air pollutant (also known as HAP or an air toxic) or 25 tons or more of any combination of HAPs. Area sources have potential air toxics emissions at less than the major source thresholds. Although area sources generally emit lower levels of air toxics than major sources, area sources are more numerous and may collectively cause adverse impacts to public health.

Because the NSPS and NESHAP adopted by reference are federal regulations, affected sources are subject to the federal requirements regardless of whether the Commission adopts the standards into the state rules. However, the CAA allows a state or local agency to implement NSPS and NESHAP as a delegated authority. Upon state adoption of the standards, the Department becomes the delegated authority for the specific NSPS or NESHAP and is the primary implementation agency in Iowa. Two local agencies, those in Polk County and Linn County, implement these standards within their counties. The Department's rules, including all compliance deadlines, are identical to the federal NSPS and NESHAP as of a specific federal publication date. With delegation authority and adoption of the federal standards into the Department's rules and the rules of Polk County and Linn County, the state and local agencies have the ability to make applicability determinations for facilities, rather than referring these decisions to EPA.

Stakeholders affected by NSPS and NESHAP typically prefer for the Department, rather than EPA, to be the primary implementation agency in Iowa. Upon adoption of the new and amended standards, the Department will work with affected facilities to provide compliance assistance as needed. Additionally, affected area sources that are small businesses are eligible for free assistance from the small business technical assistance program.

Item 8 amends the introductory paragraph of subrule 23.1(2) to adopt by reference revised NSPS published in 40 CFR Part 60. The amendment adopts the changes that EPA made to the NSPS test methods, as explained above for Item 1, through revision of the adoption date specified in the introductory paragraph of subrule 23.1(2).

Item 9 amends subrule 23.1(4) to adopt federal amendments to the NESHAP for source categories published in 40 CFR Part 63, as described below. The federal amendments are adopted by reference through revision of the adoption date specified in the introductory paragraph of subrule 23.1(4). The text in parentheses in each section heading below indicates the applicable subpart in 40 CFR Part 63 and the corresponding paragraph in subrule 23.1(4).

Surface Coating of Large Appliances (Subpart NNNN; paragraph "cn"); Printing, Coating, and Dyeing of Fabrics and Other Textiles (Subpart OOOO; paragraph "co"); and Surface Coating of Metal Furniture (Subpart RRRR; paragraph "cr")

On March 15, 2019, EPA's amendments to Part 63 for three NESHAP source categories (Surface Coating of Large Appliances; Printing, Coating, and Dyeing of Fabrics and Other Textiles; and Surface Coating of Metal Furniture) were published in the Federal Register. The regulations include provisions related to emissions during start-up, shutdown, and malfunction (SSM); electronic reporting for performance test results and compliance reports; the addition of EPA Method 18 and updates to several measurement methods; and the addition of requirements for periodic performance testing.

All three of these NESHAP source categories apply only to major sources of HAP. Currently, one facility is affected by the amendments to Subpart OOOO and two facilities are potentially affected by the amendments to Subpart RRRR. At this time, no facilities in Iowa are affected by Subpart NNNN. However, existing facilities that are area sources for HAP that increase their production and become major sources could be subject to Subpart NNNN. Additionally, new facilities that locate to Iowa, or existing facilities that change their operations to include processes covered by Subpart NNNN, would also be affected.

Surface Coating of Wood Building Products (Subpart QQQQ; paragraph "cq")

Amendments to the NESHAP for Surface Coating of Wood Building Products were published in the Federal Register on March 4, 2019. These amendments are intended to enhance the effectiveness of the existing standards and requirements for periods of SSM to be consistent with recent court decisions. The amendments to Subpart QQQQ apply only to major sources of HAP. At this time, four facilities are potentially affected by these NESHAP amendments.

Wet-Formed Fiberglass Mat Production (Subpart HHHH; paragraph "ch")

Amendments to the NESHAP for Wet-Formed Fiberglass Mat Production were published in the Federal Register on February 28, 2019. These amendments address emissions during periods of SSM; add electronic reporting; revise certain monitoring, record-keeping, and reporting requirements; and include other miscellaneous technical and editorial changes.

The amendments to NESHAP Subpart HHHH affect only major sources of HAP, and at this time no facilities in Iowa are affected by them. However, existing facilities that are area sources for HAP that increase their production and become major sources could be subject to Subpart HHHH. Additionally, new facilities that locate to Iowa, or existing facilities that change their operations to include processes covered by Subpart HHHH, would also be affected.

Leather Finishing Operations (Subpart TTTT; paragraph "ct")

Amendments to the NESHAP for Leather Finishing Operations were published in the Federal Register on February 12, 2019. These amendments address emissions during periods of SSM and provide clarifications to monitoring, record-keeping, and reporting requirements for control equipment.

The amendments to NESHAP Subpart TTTT affect only major sources of HAP, and at this time no facilities in Iowa are affected by them. However, existing facilities that are area sources for HAP that increase their production and become major sources could be subject to Subpart TTTT. Additionally, new facilities that locate to Iowa, or existing facilities that change their operations to include processes covered by Subpart TTTT, would also be affected.

Friction Materials Manufacturing (Subpart QQQQ; paragraph "dq")

Amendments to the NESHAP for Friction Materials Manufacturing were published in the Federal Register on February 8, 2019. EPA finalized minor amendments to the existing regulation and also clarified that the standards are applicable during periods of SSM. EPA also revised the deviation reporting requirements.

The amendments to NESHAP Subpart QQQQ affect only major sources of HAP, and at this time no facilities in Iowa are affected by them. However, existing facilities that are area sources for HAP that increase their production and become major sources could be subject to Subpart QQQQ. Additionally, new facilities that locate to Iowa, or existing facilities that change their operations to include processes covered by Subpart QQQQ, would also be affected.

Manufacture of Amino/Phenolic Resins (Subpart OOO; paragraph "bo")

Amendments to the NESHAP for Amino/Phenolic Resins were published in the Federal Register on October 15, 2018. In this action, EPA revised the maximum achievable control technology (MACT) standard for continuous process vents (CPVs) at existing affected sources. In addition, EPA extended

the compliance date for CPVs at existing sources. EPA also revised the requirements for storage vessels at new and existing sources during periods when an emission control system used to control vents on fixed roof storage vessels is undergoing planned routine maintenance. To improve the clarity of the NESHAP, EPA also finalized five minor technical rule corrections.

The amendments to NESHAP Subpart OOO affect only major sources of HAP, and at this time no facilities in Iowa are affected by them. However, existing facilities that are area sources for HAP that increase their production and become major sources could be subject to Subpart OOO. Additionally, new facilities that locate to Iowa, or existing facilities that change their operations to include processes covered by Subpart OOO, would also be affected.

The amendment in Item 9 also adopts the changes EPA made to the NESHAP test methods, as explained above for Item 1. The amendments to the NESHAP are adopted by reference through revision of the adoption date specified in the introductory paragraph of subrule 23.1(4).

Item 10 amends rule 567—23.5(455B), provisions for anaerobic lagoons, to update the requirements for industrial anaerobic lagoons.

Industrial anaerobic lagoons are used to treat wastewater that can contain significant organic loading. These lagoons are usually found at industries such as food processing plants or animal slaughter facilities and act as wastewater pretreatment systems. During the 1970s, the Department established the sulfate content limit and the design biochemical oxygen demand (BOD) loading rate limit. These limits were based on the information available at that time about the operating conditions that would ensure that an industrial anaerobic lagoon operated properly and minimized the release of air contaminants. The sulfate content standard applies to industrial lagoons constructed after February 22, 1979. The BOD standard applies to all industrial lagoons.

Because of advances in the design of anaerobic lagoons, higher BOD loading rates are now achievable and are allowed under wastewater construction permitting. The design of an industrial anaerobic lagoon will vary depending on the industry that is the source of the wastewater. There are other parameters besides sulfate content and BOD that can affect the proper operation of the lagoon, including water temperature, water pH, and retention time. It is thus more appropriate that the operating limits for a lagoon be established by the Department's Water Quality Bureau during its review for a wastewater construction permit rather than have the operating limits established by subrule 23.5(2) apply in all situations. Therefore, the Commission is adopting amendments to remove the sulfate content limits and the design BOD loading limits that apply to industrial anaerobic lagoons. The Commission is also adopting rules amendments to clarify that industrial anaerobic lagoons are subject to the applicable wastewater requirements specified in 567—Chapter 64.

Additionally, the Commission is adopting amendments to add the siting requirements that apply to industrial anaerobic lagoons and are currently set forth in Iowa Code section 455B.134(3)"e"(1)(b). This siting requirement was added to the Iowa Code in 1982, and applies to industrial anaerobic lagoons that were built or expanded on or after July 1, 1982. The statutory requirements established in the Iowa Code in 1982 have applied since that time and have been implemented by the Department. However, for ease of air construction permit review and to provide clarity and transparency for owners and operators of industrial anaerobic lagoons and the public, the Commission is adopting the siting requirements from the Iowa Code into subrule 23.5(2).

Item 11 amends subrule 25.1(9) to adopt the changes EPA made to the federal test methods for measuring emissions, as explained above for Item 1.

Item 12 amends subrule 30.1(1) to add new definitions for "electronic format," "electronic submittal," and "electronic submittal format," as explained above.

Items 13 and **14** amend provisions in 567—Chapter 33 applicable to prevention of significant deterioration (PSD).

The goals of the PSD program as set forth under the federal CAA are to protect human health and welfare while ensuring that economic growth can continue. Before construction, new major stationary sources and major modifications to existing major stationary sources are required to obtain a construction permit under the federal New Source Review (NSR) provisions of the CAA. In attainment areas and unclassifiable areas of the state, the relevant federal NSR program is the PSD program. The

Department operates the PSD program in Iowa through an EPA-approved state implementation plan, which includes the administrative rules in 567—Chapter 33.

Item 13 amends subrule 33.3(1) to update the definition of "volatile organic compounds" for the PSD rules, as described above for Item 1.

Item 14 adopts amendments to subrule 33.3(2) for the federal amendments to 40 CFR Part 51, Appendix W, Guideline on Air Quality Models, applicable to the PSD program set forth in 567—Chapter 33. On January 17, 2017, EPA's amendments to the guideline were published in the Federal Register. These amendments are expected to increase the efficiency and accuracy of regulatory air quality modeling demonstrations, while also providing regulatory flexibility for affected entities. The changes eliminate the need for PSD permit applicants to request approval to use certain features of EPA's regulatory air quality model, AERMOD. The revisions also increase the accuracy of model estimates in certain situations where the estimates have been shown to over predict pollutant concentrations. Additionally, the revisions allow for a screening approach for evaluating the impact of secondary formation of ozone and $PM_{2.5}$, fine inhalable particles that are 2.5 micrometers or smaller in diameter. Historically, this approach has been possible only by using highly sophisticated and expensive photochemical modeling.

The Commission did not adopt the federal amendments to Appendix W earlier because of potential legal challenges to the federal regulation. At this time, however, there is no active litigation, and EPA has addressed or is addressing several issues identified by stakeholders. The Commission is therefore now adopting the federal amendments.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 11, 2020, as **ARC 4961C**. A public hearing was held on April 13, 2020, at 1 p.m. via conference call. Four people attended the hearing to listen and ask questions about the Notice of Intended Action, but did not provide any comments. No public comments were received prior to the April 13 deadline. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 19, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. After analysis and review of this rule making, the Commission has determined that most of the changes will have a neutral fiscal impact on affected facilities, the general public, and county or local governments. Some of the amendments may benefit the private sector because they streamline current air quality programs. Affected businesses and the public benefit from up-to-date air quality requirements and increased effectiveness. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, most of the amendments will have a neutral impact on private-sector jobs. Some of the amendments may benefit the private sector because they streamline current air quality programs. For the amendments specified in Items 8 and 9, it has been determined that there may be jobs impacts to Iowa businesses. However, the amendments are only implementing federally mandated regulations. The amendments are identical to the federal regulations and will not impose any regulations on Iowa businesses not already required by federal law. In some cases, the revised federal standards being adopted provide more flexibility and potential cost savings for affected businesses, offering a positive impact on private-sector jobs. A copy of the jobs impact statement is available from the Department upon request.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 561—Chapter 10.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend rule **567—20.2(455B)**, definitions of "Anaerobic lagoon," "EPA reference method" and "Volatile organic compounds," as follows:

"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~~ off-gases.

"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 ~~August 30, 2016~~ November 14, 2018); 40 CFR 60, Appendix A (as amended through ~~August 30, 2016~~ November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through ~~August 30, 2016~~ 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 ~~August 7, 2017~~ November 14, 2018); 40 CFR 60, Appendix F (as amended through ~~August 30, 2016~~ 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).

"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 ~~August 1, 2016~~ November 28, 2018.

ITEM 2. Adopt the following **new** definition of "Electronic format" in rule **567—20.2(455B)**:

"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.

ITEM 3. Amend subrule 22.1(3), introductory paragraph, as follows:

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 ~~Department of Natural Resources, Air Quality Bureau, 502 East 9th Street, Des Moines, Iowa 50319~~ 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.

ITEM 4. Amend rule **567—22.100(455B)**, definition of "EPA reference method," as follows:

"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 ~~August 30, 2016~~ November 14, 2018); 40 CFR 60, Appendix A (as amended through ~~August 30, 2016~~ November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through ~~August 30, 2016~~ 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 ~~August 7, 2017~~ November 14, 2018); 40 CFR 60, Appendix F (as amended through ~~August 30, 2016~~ 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).

ITEM 5. Adopt the following **new** definition of "Electronic format" in rule **567—22.100(455B)**:

"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.

ITEM 6. Adopt the following **new** definition of "Electronic format" in rule **567—22.120(455B)**:

"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.

ITEM 7. Amend subrule 22.128(4) as follows:

22.128(4) *Submission of copies.* ~~Two copies~~ One copy of all permit applications shall be presented or mailed to the ~~Air Quality Bureau, Iowa Department of Natural Resources, 502 East 9th Street, Des Moines, Iowa 50319~~ 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.

ITEM 8. Amend subrule 23.1(2), introductory paragraph, as follows:

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 ~~August 7, 2017,~~ 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.

ITEM 9. Amend subrule 23.1(4), introductory paragraph, as follows:

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 ~~August 3, 2018,~~ 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.

ITEM 10. Amend rule 567—23.5(455B) as follows:

567—23.5(455B) Anaerobic lagoons.

23.5(1) No change.

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 ~~gpd~~ 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.

~~(1) The sulfate content of the water supply shall not exceed 250 mg/l. However, this paragraph does not apply to an expansion of an industrial anaerobic lagoon facility which was constructed prior to February 22, 1979.~~

~~(2) The design loading rate for the total lagoon volume shall not be less than 10 pounds nor more than 20 pounds of biochemical oxygen demand (five day) per thousand cubic feet per day.~~

b. Lagoons designed to treat more than 100,000 ~~gpd~~ 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.

~~(1) The sulfate content of the water supply shall not exceed 100 mg/l. However, this paragraph does not apply to an expansion of an industrial anaerobic lagoon facility which was constructed prior to February 22, 1979.~~

~~(2) The design loading rate for the total lagoon volume shall not be less than 10 pounds nor more than 20 pounds of biochemical oxygen demand (five day) per thousand cubic feet per day.~~

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.

ITEM 11. Amend subrule 25.1(9) as follows:

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 ~~August 30, 2016~~ November 14, 2018); 40 CFR 60, Appendix A (as amended through ~~August 30, 2016~~ November 14, 2018); 40 CFR 61, Appendix B (as amended through August 30, 2016); and 40 CFR 63, Appendix A (as amended through ~~August 30, 2016~~ 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 ~~August 7, 2017~~ November 14, 2018); 40 CFR 60, Appendix F (as amended through ~~August 30, 2016~~ 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 ~~specification~~ specifications and quality assurance ~~procedure is~~ procedures are conducted.

c. No change.

ITEM 12. Adopt the following **new** definition of "Electronic format" in subrule **30.1(1)**:

"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.

ITEM 13. Amend subrule **33.3(1)**, definition of "Volatile organic compounds," as follows:

"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 ~~August 1, 2016~~ November 28, 2018.

ITEM 14. Amend subrule 33.3(2), introductory paragraph, as follows:

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 ~~November 9, 2005~~ January 17, 2017, are adopted by reference.

[Filed 5/21/20, effective 7/22/20]
[Published 6/17/20]
EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5053C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to establishing a safety zone on Beaver Creek

The Natural Resource Commission (Commission) hereby amends Chapter 40, "Boating Speed and Distance Zoning," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 321G.2, 321I.2, 462A.3 and 462A.26.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 321G.2, 321I.2, 462A.3 and 462A.26.

Purpose and Summary

Beaver Creek is a small river with increasing recreational use that is encouraged in part by publicity surrounding the City of Johnston's sponsorship of a recreational water trails plan. Beaver Creek flows through the Camp Dodge military reservation in Polk County. As recreation has increased on Beaver Creek, concerns among Iowa National Guard personnel at Camp Dodge have increased because of the potential for accidental injury and death at the facility's live-fire practice range. Beaver Creek is within a "surface danger zone," which is the area designated within the Camp Dodge training complex for containment of projectiles, fragments, debris, and components resulting from the firing, launching, or detonation of weapon systems, including explosives and demolitions. Currently, members of the public are potentially unaware of this danger when passing through the Camp Dodge facility via Beaver Creek. This rule making creates a safety zone into which access may be prohibited when clearly identified by signage in order to reduce risk to public safety. If at some future date live-fire ammunition is no longer used during training exercises at Camp Dodge, the Commission may seek to rescind this rule.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 15, 2020, as **ARC 4855C**. A public hearing was held on February 4, 2020, at 2:30 p.m. at the Wallace State Office Building, Des Moines, Iowa. One member from Camp Dodge attended in support of the new rule. No changes were requested. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making action is adopted:

Adopt the following **new** rule 571—40.61(321G,321I,462A):

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.

[Filed 5/21/20, effective 7/22/20]
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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5054C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to virtual fishing tournaments

The Natural Resource Commission (Commission) hereby amends Chapter 44, "Special Events and Fireworks Displays," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 455A.5(6), 462A.16 and 481A.39.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 455A.5(6), 462A.16 and 481A.39.

Purpose and Summary

This rule making expands the existing definition of "fishing tournament" found in rule 571—44.2(321G,321I,461A,462A,481A) by adding language to include virtual fishing tournaments, also known as "catch-photo-release" tournaments. Virtual fishing tournaments are increasing in popularity; however, there is no allowance for these events within the current rules. The amendments are necessary because Iowa Code section 462A.16 requires that all tournaments be authorized by the Commission.

The rule making also adds definitions of "aggregated virtual fishing tournament" and "distributed virtual fishing tournament." An aggregated virtual fishing tournament is similar to a traditional fishing tournament in which participants gather at one location to fish, except that it does not have a weigh-in at the end of the day because all fish are immediately measured, photographed, and released. A distributed virtual fishing tournament, usually organized as an online contest, occurs on multiple bodies of water and can last for weeks or months. This type of tournament has a minimal impact on natural resources and fish populations, and the Commission wishes to encourage the growth of these events in Iowa. The rule making allows distributed virtual fishing tournaments to occur at more than one location and last longer than the currently established nine-day period for a single special event. In addition, the amendments exempt both types of virtual fishing tournaments from paying the special event permit application fee.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4924C**. Five public hearings were held across the state on March 5, 2020. Attendance at the public meetings was low, and most of the comments were received by email.

A news release was issued on February 12, 2020, soliciting public comment on the proposed rule making and inviting the public to participate in the five public hearings. This news release was sent to approximately 400 news outlets in Iowa, along with about 28,500 subscribers to *Iowa Outdoor News* and 105,800 subscribers to *Fishing News*. Of the 21 public comments received, 100 percent supported the rule making. In review of the comments, some of the supporters noted they would like to see the permit fee not be waived for aggregated virtual fishing tournaments.

Changes from the Notice of Intended Action have been made. After consideration of the comments, a change has been made so that the final rule making does not waive the permit fee for aggregated virtual fishing tournaments.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule making is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend rule **571—44.2(321G,321I,461A,462A,481A)**, definition of "Fishing tournament," as follows:

"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.

ITEM 2. Amend subrule 44.5(4) as follows:

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.

ITEM 3. Amend rule 571—44.8(321G,321I,461A,462A,481A) as follows:

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; ~~and~~ department-sponsored youth fishing days; and distributed virtual fishing tournaments.

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ARC 5055C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to the application of chemicals to public waters

The Natural Resource Commission (Commission) hereby amends Chapter 54, "Restrictions on Introduction and Removal of Plant Life," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 455A.5(6) and chapters 461A and 462A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapters 455A, 461A and 462A.

Purpose and Summary

This rule making allows cities and counties to apply chemicals to public waters, as defined by rule 571—13.3(455A,461A), for the removal of aquatic plants for navigational and recreational purposes. This application will be subject to a permit issued by the Department of Natural Resources (Department) and a Department-approved vegetation management plan. Currently, only Department staff may apply chemicals for plant control for navigational or recreational purposes.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4920C**. Five public hearings were held across the state on March 5, 2020. Attendance at the public meetings was low, and most of the comments were received by email.

A news release was issued on February 12, 2020, soliciting public comment on the proposed rule making and inviting the public to participate in the five public hearings being held. This news release was sent to approximately 400 news outlets in Iowa, along with about 28,500 subscribers to *Iowa Outdoor News* and 105,800 subscribers to *Fishing News*. Eleven public comments were received. Ten supported this rule making, while one expressed concern that removal of aquatic vegetation pursuant to the new provision could negatively impact fishing.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making action is adopted:

Amend subrule 54.5(1) as follows:

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 ~~rules in~~ 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.

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ARC 5056C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to fishing regulations

The Natural Resource Commission (Commission) hereby amends Chapter 81, "Fishing Regulations," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 481A.38.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 481A.38.

Purpose and Summary

This rule making standardizes the methods used for establishing length limits and other fishing regulations that are specific to a site (waterbody) and extends the Missouri River/Big Sioux River paddlefish season by three days. Currently, site-specific regulations exist as administrative rules within Chapter 81. This rule making allows the Department of Natural Resources (Department) to make changes to site-specific regulations, or implement new regulations, by posting such regulations on signage at the relevant waterbodies. The Department already uses onsite signage to alert anglers to various regulations, and this method is highly successful and well-accepted by the state's anglers. These changes are explained individually and in greater detail below.

Subrule 81.2(2) prescribes length limits and catch and release regulations for black bass. The changes to this subrule simplify how the various length limits are listed in the rule and allow the Department greater flexibility in managing bass populations by designating site-specific restrictions via posting signage at the respective waterbodies. The alternative is to conduct rule making every time the Department determines that a length limit or other similar restriction at a specific waterbody should be changed. This is unnecessarily burdensome. The practice of posting length limits and catch and release requirements at waterbodies is already widespread, effective, and accepted by anglers.

Subrule 81.2(3) provides daily bag limits, possession limits, and length limits for walleye. Paragraph 81.2(3)"b" currently allows the Department to establish site-specific walleye regulations by posting signage at the waterbody. When paragraph 81.2(3)"b" was adopted in 2014, allowing for this method of implementing new regulations, the existing site-specific regulations for walleye in the Mississippi River were inadvertently left in paragraph 81.2(3)"c." The change to subrule 81.2(3) removes the Mississippi River specific regulations by striking paragraph 81.2(3)"c," at which point the existing provision in paragraph 81.2(3)"b," allowing for regulation adoption via signage, would apply to the Mississippi River. This change allows the Department to more efficiently institute management regulations (length limits, etc.) for walleye on the Mississippi River and brings statewide consistency to how walleye regulations are implemented.

Subrule 81.2(4) provides various regulations applicable to the paddlefish season on the Missouri River and Big Sioux River. This rule making amends subparagraph 81.2(4)"b"(1) by changing "February 4"

to "February 1." This change provides three additional days for anglers to harvest paddlefish, without negatively impacting the population.

Subrule 81.2(5) currently provides various regulations applicable to trout fishing. The subrule's single paragraph covers multiple species of trout, streams, length limits, and tackle limitations. This rule making greatly simplifies this subrule by striking the paragraph and replacing it with new provisions that (1) allow the Department to post via signage seasons, bag or possession limits, length limits, catch and release regulations, and tackle regulations specific to a waterbody at that waterbody and (2) provide a simplified list of standard trout regulations applicable to all waterbodies that do not have posted regulations.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4922C**. Five public hearings were held across the state on March 5, 2020. Attendance at the public meetings was low, and most of the comments were received by email.

A news release was issued on February 12, 2020, soliciting public comment on the proposed rule making and inviting the public to participate in the five public hearings being held. This news release was sent to approximately 400 news outlets in Iowa, along with about 28,500 subscribers to *Iowa Outdoor News* and 105,800 subscribers to *Fishing News*. Nine public comments were received; all supported the rule making.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 81.2(2) as follows:

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 ~~except as otherwise posted~~. ~~On federal flood control reservoirs, a 15-inch minimum length limit shall apply on black bass at Coralville, Rathbun, Saylorville, and Red Rock. All black bass caught from Lake Wapello, Davis County, and Brown's Lake, Jackson County, must be immediately released alive.~~

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. ~~All black bass caught from the following stream segments must be immediately released alive:~~

~~1. Middle Raccoon River, Guthrie County, extending downstream from below Lennon Mills Dam at Panora as posted to the dam at Redfield.~~

~~2. Maquoketa River, Delaware County, extending downstream from below Lake Delhi Dam as posted to the first county gravel road bridge.~~

~~3. Cedar River, Mitchell County, extending downstream from below the Otranto Dam as posted to the bridge on County Road T26 south of St. Ansgar.~~

~~4. Upper Iowa River, Winneshiek County, extending downstream from the Fifth Street bridge in Decorah as posted to the Upper Dam.~~

ITEM 2. Amend subrule 81.2(3) as follows:

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.

~~*c. Mississippi River.* A 15-inch minimum length limit shall apply. All walleye from 20 inches to 27 inches in length that are caught from Mississippi River Pools 12 through 20 must be immediately released alive. No more than one walleye greater than 27 inches in length may be taken per day from Pools 12 through 20.~~

ITEM 3. Amend subparagraph **81.2(4)"b"(1)** as follows:

(1) There shall be an open season from February 4 1 through April 30.

ITEM 4. Amend subrule 81.2(5) as follows:

81.2(5) ~~Special trout regulations. A 14-inch minimum length limit shall apply on brown trout, rainbow trout, and brook trout in Spring Branch Creek, Delaware County, from the spring source to County Highway D5X as posted, and on brown trout only in portions of Bloody Run Creek, Clayton County, where posted. All trout caught from the posted portion of Waterloo Creek, Allamakee County, Hewitt and Ensign Creeks (Ensign Hollow), Clayton County, McLoud Run, Linn County, and South Pine Creek, Winneshiek County, and all brown trout caught from French Creek, Allamakee County, must be immediately released alive. Fishing in the posted area of Spring Branch Creek, Bloody Run Creek, Waterloo Creek, Hewitt and Ensign Creeks (Ensign Hollow), South Pine Creek, McLoud Run, and French Creek shall be by 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.~~ 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.

[Filed 5/26/20, effective 7/22/20]
[Published 6/17/20]
EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5057C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to waterfowl hunting seasons and zones

The Natural Resource Commission (Commission) hereby amends Chapter 91, "Waterfowl and Coot Hunting Seasons," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 455A.5(6), 481A.38, 481A.39 and 481A.48.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 481A.48.

Purpose and Summary

Chapter 91 contains the regulations for hunting waterfowl and coot and includes season dates, bag limits, possession limits, shooting hours, and areas open to hunting. These amendments modify the waterfowl hunting zones and adjust the season dates to comply with what the Commission anticipates the 2021-2026 federal regulations will be after having met with the United States Fish and Wildlife Service (USFWS) in August 2019 at the Mississippi Flyway Council and reviewing the preliminary proposed regulations contained in the Federal Register (preliminary proposed in 84 Fed. Reg. 199, 55120-55129 (Oct. 15, 2019)).

More specifically, the season structure that the Department of Natural Resources (Department) is adopting uses the maximum number of days provided by the USFWS. These days are distributed across a wide range of season dates based on a waterfowl migration survey that the Department conducts each fall, an analysis of hunter participation and hunter satisfaction, and a 2019 waterfowl hunter opinion survey. Season dates differ between waterfowl hunting zones and allow for a period of rest before the regular duck seasons and the youth waterfowl hunting season. Hunter surveys and comments show a wide range of preferences; therefore, the season structure offers a wide range of dates in an attempt to accommodate all hunting preferences.

The boundary modifications to the waterfowl hunting zones extend later season dates across southern Iowa in response to hunter interest, while maintaining early and mid-season hunting opportunities, particularly in central and northern Iowa.

The extension of the light goose conservation order is in response to hunter requests regarding the effect of particularly harsh weather during the spring of 2018, which precluded widespread hunting of light geese in northern Iowa until late April of that year.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4914C**. A public hearing was held on March 3, 2020, at 12 noon at the Wallace State Office Building, Des Moines, Iowa. Two people attended the hearing and asked questions about the proposed amendments but did not offer any comments.

Ninety-four individuals submitted comments during the public comment period covering 26 issues relating to waterfowl hunting in Iowa. The most common comments received included opposition to a zone reconfiguration (21), support for a zone reconfiguration (12), support for October hunting dates (14), opposition to the special September teal season (14), support for the historic five-day September season (5), and support for later duck seasons in general (5).

Additionally, the Department held annual Hunter Listening Session meetings at 17 locations across the state during the open comment period. Approximately 480 hunters attended these meetings and offered 144 waterfowl-related comments covering 44 topics. The most common comments heard at these meetings included support for the current Canada goose hunting season structure (28), support for later duck seasons (15), opposition to the special September teal season (13), opposition to a zone reconfiguration (12), and support for a zone reconfiguration (11).

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrules 91.1(1) to 91.1(5) as follows:

91.1(1) *Zone boundaries.* The following zone boundaries apply in the time frames noted:

a. ~~The~~ 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.

ITEM 2. Amend subrules 91.3(1) to 91.3(4) as follows:

91.3(1) *Zone boundaries.* The following zone boundaries apply in the time frames noted:

a. ~~The~~ 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.

ITEM 3. Amend subrule 91.3(8), introductory paragraph, as follows:

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 ~~April 15~~ May 1.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5058C

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Rule making related to restitution for pollution causing injury to wild animals

The Natural Resource Commission (Commission) hereby amends Chapter 113, "Restitution for Pollution Causing Injury to Wild Animals," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 455A.5(6) and 481A.151.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 455A.5(6) and 481A.151.

Purpose and Summary

Iowa Code section 481A.151 authorizes the Commission to adopt rules incorporating the methods and values published by the American Fisheries Society (AFS) for use by the Department of Natural Resources (Department) when conducting fish kill counts and assessing restitution for damages to the state's natural resources and wildlife. The Commission has done so in Chapter 113. This amendment updates the definition of "AFS" in rule 571—113.2(481A) by changing "Special Publication 30" to "Special Publication 35." Special Publication 35 is the most current version of the AFS publication regarding fish and freshwater mollusk counting methods and restitution valuation. The alternative of not adopting the newest version of the AFS publication would require the Department to use a document that is no longer considered the best available publication for these purposes.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on February 12, 2020, as **ARC 4921C**. Five public hearings were held across the state on March 5, 2020. Attendance at the public meetings was low, and most of the comments were received by email.

A news release was issued on February 12, 2020, soliciting public comment on the proposed rule making and inviting the public to participate in the five public hearings being held. This news release was sent to approximately 400 news outlets in Iowa, along with about 28,500 subscribers to *Iowa Outdoor News* and 105,800 subscribers to *Fishing News*. Of the 21 public comments received, 100 percent supported the rule making.

No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Commission on May 14, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa. A copy of the fiscal impact statement is available from the Department upon request.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found. A copy of the jobs impact statement is available from the Department upon request.

Waivers

This rule is subject to the waiver provisions of 571—Chapter 11. Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Commission for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making action is adopted:

Amend rule **571—113.2(481A)**, definition of "AFS," as follows:

"AFS" means the Special Publication ~~30~~ 35, "Investigation and Monetary Values of Fish and Freshwater ~~Mussel~~ Mollusk Kills," published by the American Fisheries Society.

[Filed 5/26/20, effective 7/22/20]
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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5059C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to radiation machines and radioactive materials

The Public Health Department hereby amends Chapter 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials," Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials," Chapter 40, "Standards for Protection Against Radiation," Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapter 136C.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136C.

Purpose and Summary

These amendments reflect current federal regulations, amend rules to correct errors discovered by staff, and amend rules to meet U.S. Nuclear Regulatory Commission (USNRC) compatibility requirements pursuant to the stipulations of the state of Iowa's status as a USNRC agreement state. Additional amendments clarify rules related to new technology for dosimetry processes that have

become available and radiation machines used on humans for security purposes at correctional facilities and jails.

Iowa rules must maintain compatibility as defined by the USNRC. Most of these amendments require the wording to be the same as or substantially the same as that published in the CFR by the USNRC. The dosimetry and machine-related rules are two areas that have been prohibited in the current rules and have been allowed through a variance process for the last couple of years.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 15, 2020, as **ARC 4856C**. No public comments were received. The USNRC provided five comments requesting minor changes to Items 2, 48, and 55. In response to the USNRC comments, the following changes were made from the Notice:

In Item 2: The phrase "in accordance with rule 641—37.7(136C)" was added to the new sentence in paragraph 37.23(2)"b."

In Item 48: The phrase "for three years" has been stricken, and the following phrase was added in its place: "until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit."

In Item 53: The phrase "oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for" was added to the first sentence in subparagraph 41.2(81)"c"(3), and the phrase "oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide (I-131) for" was added to the first sentence in subparagraph 41.2(82)"c"(3).

In Item 55: The word "with" was stricken and the word "within" was added in its place in subparagraph 41.2(87)"h"(2).

In Item 56: In 41.2(89)"b"(3)"2," a citation to subrule 41.2(59) was corrected to instead cite subrule 41.2(69) and the words "NRC or" were added so that the language now reads as follows: "or equivalent NRC or agreement state requirements."

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 13, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 37.1(4) as follows:

37.1(4) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 2. Amend paragraph **37.23(2)"b"** as follows:

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).

ITEM 3. Amend subrule 37.27(3) as follows:

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 ~~Facilities and Security~~ Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05-B32M~~ 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 ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630)829-9565, or by email to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~www.nrc.gov/site-help/e-submittals.html~~ 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 ~~Security Branch, Division of Facilities and Security at 1-301-492-3531~~ 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 ~~Electronic Submittals page at www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)~~ 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.

ITEM 4. Amend subrule 37.43(4) as follows:

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, ~~and~~ implementing procedures, and the list of individuals that have been approved for unescorted access.

c. Before granting an individual access to the security plan, ~~or~~ 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, ~~or~~ 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, ~~or~~ 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, ~~or~~ 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, ~~or~~ 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, ~~or~~ 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, ~~and~~ 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, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.

ITEM 5. Amend rule 641—37.77(136C) as follows:

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 ~~Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs,~~ 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, ~~Division of Security Policy,~~ 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 ~~of Nuclear Security~~, 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, ~~Division of Security Policy,~~ 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, ~~Division of Security Policy,~~ 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).

ITEM 6. Amend subrule 38.1(2) as follows:

38.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 7. Adopt the following **new** definitions of "FDA" and "Sealed Source and Device Registry" in rule **641—38.2(136C)**:

"FDA" means the Food and Drug Administration.

"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.

ITEM 8. Amend rule **641—38.2(136C)**, definitions of "Agreement state," "Decay-in-storage," "Preceptor" and "Reportable medical event," as follows:

"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.

"Decay-in-storage" means the holding of radioactive material having half-lives of less than or equal to 120 days~~, except Cobalt-57,~~ 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.

"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, ~~or~~ a radiation safety officer, or an associate radiation safety officer.

"Reportable medical event" means the medical event~~, except for an event that results from patient intervention, in which the administration of by-product material or radiation from by-product material results in~~:

~~*a.* 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~~

~~1. The total dose delivered differs from the prescribed dose by 20 percent or more;~~

~~2. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or~~

~~3. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.~~

~~*b.* 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:~~

~~1. An administration of the wrong radioactive drug containing by-product material;~~

~~2. An administration of a radioactive drug containing by-product material by the wrong route of administration;~~

~~3. An administration of a dose or dosage to the wrong individual or human research subject;~~

~~4. An administration of a dose or dosage delivered by the wrong mode of treatment; or~~

~~5. A leaking sealed source.~~

~~*c.* A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

~~*d.* An event resulting from intervention of a patient or human research subject in which administration of by-product material or radiation from by-product material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.~~

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 discontiguous 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.

ITEM 9. Rescind the definition of "Teletherapy" in rule **641—38.2(136C)**.

ITEM 10. Amend rule 641—38.6(136C) as follows:

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.

ITEM 11. Amend subrule 38.8(2) as follows:

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.

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	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	*In-Vitro* 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	~~T~~ R	Note 5
(3.M.)	03620	RD2	Research & Development – Other	$4,375	3	$4,000
(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	~~7~~ 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 ~~"T"~~ "R" is a ~~telephonic~~ 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.

ITEM 12. Amend subrule 38.8(12) as follows:

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.

ITEM 13. Amend subrule 38.9(1) as follows:

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~~, to impose serious misdemeanor penalties pursuant to Iowa Code section 136B.5 or to impose simple misdemeanor penalties pursuant to Iowa Code section 136D.8~~.

ITEM 14. Amend subrule 39.1(3) as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 15. Amend paragraph **39.3(2)"a"** as follows:

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 ~~van~~ 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).

ITEM 16. Amend subparagraph **39.4(21)"e"(3)** as follows:

(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.

ITEM 17. Amend subparagraph **39.4(22)"d"(3)** as follows:

(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. to 12. No change.

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. and 15. No change.

ITEM 18. Amend subparagraph **39.4(29)"j"(1)** as follows:

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing ~~by-product~~ byproduct material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. to 3. No change.

4. The applicant ~~satisfies~~ 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.

ITEM 19. Amend subparagraph **39.4(29)"j"(2)** as follows:

(2) A licensee as described by 39.4(29)*"j"*(1)"2":

1. to 4. No change.

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"* ~~with the written attestation signed by a preceptor as required by 641—paragraph 41.2(78)*"e"*~~; 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.

ITEM 20. Renumber subparagraphs **39.4(29)"j"(3)** and **(4)** as **39.4(29)"j"(4)** and **(5)**.

ITEM 21. Adopt the following **new** subparagraph **39.4(29)"j"(3)**:

(3) A licensee shall satisfy the labeling requirements in 39.4(29)*"j."*

ITEM 22. Amend paragraph **39.4(32)"e"** as follows:

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."*

ITEM 23. Amend subrule 40.1(5) as follows:

40.1(5) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 24. Amend subrule 40.16(1) as follows:

40.16(1) If the licensee or registrant is required to monitor pursuant to both ~~40.19(1)~~ 40.37(1) and ~~40.19(2)~~ 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 ~~40.19(1)~~ 40.37(1), or only pursuant to ~~40.19(2)~~ 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.

ITEM 25. Amend subrule 40.37(3) as follows:

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 the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device shall be near the midline of the body, under the apron;~~

~~*b.*~~ *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;

~~*c.*~~ *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;

~~*d.*~~ *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.

ITEM 26. Amend paragraph **41.2(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 27. Adopt the following **new** definitions of "Associate radiation safety officer," "Ophthalmic physicist," "Stereotactic radiosurgery" and "Teletherapy" in subrule **41.2(2)**:

"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.

"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.

"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.

ITEM 28. Amend subrule **41.2(2)**, definition of "Radiation safety officer," as follows:

"Radiation safety officer" means an individual who, in addition to the definition in 641—38.2(136C)~~, meets the requirements of 41.2(77) and 41.2(65)*"a,"* or 41.2(65)*"c"*(1), or before May 3, 2006, meets the requirements in 10 CFR 35.900(a) and 10 CFR 35.59; or is identified as a radiation safety officer on a specific medical use license issued by Iowa, the NRC, or agreement state or a medical use permit issued by an NRC master material licensee.~~:

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.

ITEM 29. Rescind the definition of "Teletherapy physicist" in subrule **41.2(2)**.

ITEM 30. Amend subrules 41.2(4) and 41.2(5) as follows:

41.2(4) *License amendments.*

a. A licensee shall apply for and receive a license amendment:

~~*a.*~~ (1) Before using ~~radioactive~~ byproduct material for a method or type of medical use not permitted by the license issued under this rule;

~~*b.*~~ (2) Before permitting anyone~~, except a visiting authorized user or visiting authorized nuclear pharmacist described in 41.2(12),~~ 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);

~~*c.*~~ (3) Before changing a radiation safety officer~~, teletherapy physicist or authorized medical physicist~~;

(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;

~~*d.*~~ (5) Before receiving ~~radioactive~~ byproduct material in excess of the amount authorized on the license;

~~*e.*~~ (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.

~~*f.* Before changing statements, representations, and procedures which are incorporated into 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 provide to the agency a copy of the board certification, the NRC or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as a visiting authorized user or a visiting authorized nuclear pharmacist.~~

~~*b.* A licensee shall notify the agency by letter no later than 30 days after:~~

~~(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or~~

~~(2) The licensee's mailing address changes.~~

~~*c.* The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.~~

~~*d.* 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)*"b"*;~~

~~(2) The provisions of 41.2(4)*"e"* regarding additions to or changes in the areas of use only at the addresses specified in the license;~~

~~(3) The provision of 41.2(5)*"a"*;~~

~~(4) The provisions of 41.2(5)*"b"*(1) for authorized user or an authorized nuclear pharmacist.~~

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).

ITEM 31. Amend paragraphs **41.2(10)"b"** and **"c"** as follows:

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 authorized user or~~ 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).

ITEM 32. Amend subrule 41.2(12) as follows:

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 ~~an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission~~ 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 ~~as an authorized user~~ 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 ~~agency (~~ NRC or agreement state~~, licensing state or U.S. Nuclear Regulatory Commission)~~ 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.

ITEM 33. Amend subrule 41.2(14) as follows:

41.2(14) *Records and reports of ~~misadministrations and~~ reportable medical events.*

a. When a ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ 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 ~~misadministration or~~ reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. and 2. No change.

c. Rescinded IAB 4/4/01, effective 5/9/01.

d. Each licensee shall retain a record of ~~each misadministration for ten years and~~ 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. and *f.* No change.

ITEM 34. Amend paragraph **41.2(17)"e"** as follows:

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) to (4) No change.

ITEM 35. Amend subrule 41.2(20) as follows:

41.2(20) *Authorization for calibration and reference sources.*

a. Any person authorized by 41.2(3) for medical use of ~~radioactive~~ byproduct material may receive, possess, and use the following ~~radioactive~~ byproduct material for check, calibration and reference use:

~~*a.*~~ (1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the ~~U.S. Nuclear Regulatory Commission~~ NRC, agreement state or licensing state and that do not exceed 30 millicuries (1.11 GBq) each;

~~*b.*~~ (2) Any ~~radioactive~~ 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);

~~*c.*~~ (3) Any ~~radioactive~~ 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

~~*d.*~~ (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.

ITEM 36. Rescind and reserve subrule **41.2(32)**.

ITEM 37. Amend subrule 41.2(34) as follows:

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 ~~preparing:~~ 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."*

~~(1) Technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract; or~~

~~(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day.~~

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."*

~~*c.*~~ *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.

~~*d.*~~ *e.* A licensee shall report ~~immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(34)*"a"*(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34)*"a"*(2).~~ 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."*

ITEM 38. Rescind and reserve subrule **41.2(36)**.

ITEM 39. Amend subrule 41.2(37), introductory paragraph, as follows:

41.2(37) *Use of unsealed ~~by-product~~ byproduct material for which a written directive is required.* A licensee may use any unsealed ~~by-product~~ 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:

ITEM 40. Amend subrule 41.2(38) as follows:

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 ~~keep~~ maintain a record of ~~individuals receiving instruction required by 41.2(38)*"a,"*~~ 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.

ITEM 41. Amend subrule 41.2(39), catchwords, as follows:

41.2(39) *Safety precautions for radiopharmaceutical therapy and hospitalization.*

ITEM 42. Rescind and reserve subrule **41.2(40)**.

ITEM 43. Amend subrule 41.2(41) as follows:

41.2(41) *Use of sealed sources for diagnosis.* ~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.~~

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.

ITEM 44. Rescind and reserve subrule **41.2(42)**.

ITEM 45. Amend subrules 41.2(43) to 41.2(45) as follows:

41.2(43) *Use of sources for manual brachytherapy.* A licensee shall use only brachytherapy sources ~~for therapeutic medical uses~~:

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 ~~implant therapy~~ 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 ~~individuals receiving instruction required by 41.2(44)*"a,"*~~ 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 ~~implant therapy~~ manual brachytherapy a licensee shall:

(1) to (6) No change.

b. No change.

ITEM 46. Rescind and reserve subrule **41.2(48)**.

ITEM 47. Amend subrule 41.2(49) as follows:

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.* ~~A licensee shall use sealed sources in photon-emitting remote afterloader units,~~

~~teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses as approved in the Sealed Source and Device Registry or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.~~

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.

ITEM 48. Amend subrule 41.2(52) as follows:

41.2(52) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma ~~sterotactic~~ stereotactic radiosurgery units.*

a. to *c.* No change.

d. A licensee shall ~~provide~~:

(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)~~ 1. The procedures identified in 41.2(52)*"a"*(4); and

~~(2)~~ 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)*"d,"*~~ 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)*"a"*(4) and~~ 41.2(52)*"d"*(2) shall be retained ~~for three years~~ until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

ITEM 49. Amend subrule 41.2(53), catchwords, as follows:

41.2(53) *Safety precautions for remote afterloader units, teletherapy units, and gamma ~~sterotactic~~ stereotactic radiosurgery units.*

ITEM 50. Rescind and reserve subrule **41.2(54)**.

ITEM 51. Amend subrules 41.2(64) to 41.2(75) as follows:

41.2(64) ~~*Five-year inspection*~~ *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 ~~teletherapy~~ each source replacement ~~or at intervals not to exceed five~~

~~years, whichever comes first,~~ to ~~ensure~~ 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 ~~agency,~~ NRC or an agreement state~~, or the U.S. Nuclear Regulatory Commission~~.

c. A licensee shall maintain a record of the full inspection and servicing for the duration of the ~~license~~ 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 ~~this agency,~~ the NRC~~,~~ or an agreement state and who meets the requirements in 41.2(65)*"d."* ~~and *"e."* (~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or an agreement state ~~must be~~ 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 ~~agency,~~ 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 ~~completed~~:

(1) Completed a structured educational program consisting of both:

~~(1)~~ 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. Radiation biology; and~~

~~5. Radiation dosimetry; and~~

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Radiation biology; and
- Radiation dosimetry; and

~~(2)~~ 2. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an ~~agency,~~ NRC~~,~~ or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of ~~radioactive~~ byproduct material ~~involving~~. 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:

~~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 instruments used to measure radionuclides;~~

~~3. Securing and controlling radioactive material;~~

~~4. Using administrative controls to avoid mistakes in the administration of radioactive material;~~

~~5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;~~

~~6. Using emergency procedures to control radioactive material; and~~

~~7. Disposing of radioactive material; or~~

- 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 ~~agency,~~ NRC~~,~~ or an agreement state under ~~41.2(74) and~~ 41.2(74)*"a,"* has experience in radiation safety ~~for~~ aspects of similar types of use of ~~radioactive~~ 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 ~~who~~ meets the requirements in 41.2(65)*"d"* ~~and *"e"*~~; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's~~ an NRC or agreement state license ~~and~~, 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 ~~radioactive~~ byproduct material for which the licensee seeks the approval of the individual ~~has~~ as the radiation safety officer ~~responsibilities~~ or associate radiation safety officer and meets the requirements in 41.2(65)*"d"*; ~~and~~ 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 obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in 41.2(65)*"e"* and 41.2(65)*"a"*(1)"1" and "2" or 41.2(65)*"a"*(2)"1" and "2" or 41.2(65)*"b"*(1) or 41.2(65)*"c"*(1), and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and~~

~~*e.*~~ *d.* Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee ~~is seeking~~ 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) *Training for experienced radiation safety officer.* Rescinded IAB 3/29/06, effective 5/3/06.

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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(67)*"c."* (~~. The names of ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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~~, signed by 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,~~ that the individual has satisfactorily completed the requirements in ~~41.2(67)*"a"*(1) or~~ 41.2(67)*"c"*(1) and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user ~~for the medical uses authorized in~~ 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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(68)*"c."* (~~. The names of ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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~~, and 41.2(69)~~; 41.2(75); or equivalent NRC or agreement state requirements~~, involving~~:. 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~~, signed by 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; 41.2(75); or equivalent NRC or agreement state requirements,~~ that the individual has satisfactorily completed the requirements in ~~41.2(68)*"a"*(1) or~~ 41.2(68)*"c"*(1) and ~~has achieved a level of competency sufficient to~~

~~function~~ 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 ~~by product~~ 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 ~~radioactive~~ 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 ~~agency,~~ NRC~~,~~ or an agreement state and who meets the requirements in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph~~, and 41.2(69)*"b"*(2)~~. ~~(~~The names of the ~~specialty boards~~ board certificates that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~involving~~ 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 ~~either~~ any ~~beta emitter or a photon-emitting radionuclide with a~~ 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; ~~or~~ and

~~– Parenteral administration of any other radionuclide 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)*"a"*(1) and 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or~~ 41.2(69)*"b"*(1)~~,~~ and ~~has achieved a level of competency sufficient to function~~ 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 written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)*"b"* must 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 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 ~~agency,~~ NRC~~,~~ or an agreement state~~, and who meets the requirements in 41.2(70)*"b"*(3)~~. (~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ 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 ~~institution~~ 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~~, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements,~~ that the individual has satisfactorily completed the requirements in ~~41.2(70)*"a"*(1) or~~ 41.2(70)*"b"*(1) and (2)~~,~~ and ~~has achieved a level of competency sufficient to function~~ 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 ~~has achieved a level of competency sufficient to function~~ 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 ~~for use in~~ 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)*"b"* and~~ 41.2(72)*"c"* and *"d"* and whose certification has been recognized by the ~~agency,~~ NRC~~,~~ or an agreement state. ~~(~~The names of the ~~specialty boards~~ board certificates that have been recognized by the ~~agency,~~ 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

~~*b.*~~ *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

~~*c.*~~ *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 ~~agency,~~ NRC~~,~~ or an agreement state~~,~~ and who meets the requirements in ~~41.2(73)*"b"*(3) and~~ 41.2(73)*"c."* ~~(~~The names of ~~the specialty boards~~ board certification that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~institution~~ 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)*"a"*(1) or~~ 41.2(73)*"b"*(1) and (2)~~,~~ and 41.2(73)*"c,"* and ~~has achieved a level of competency sufficient to function~~ 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 ~~written~~ attestation must be ~~signed by a~~ 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; ~~and~~ 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)*"b"*(2) and~~ 41.2(74)*"c."* ~~(~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or

agreement state ~~must be~~ 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 ~~agency,~~ 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)*"a"*(1) and (2) and 41.2(74)*"c"* or~~ 41.2(74)*"b"*(1) and ~~41.2(74)*"c,"*~~ *"c"* and ~~has achieved a level of competency sufficient to function~~ 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~~; and~~.

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 as a radiation safety officer, teletherapy or medical physicist, or nuclear pharmacist on an agency, NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).~~ 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) ~~An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on the agency, NRC, or agreement state license or permit issued by the agency, NRC, or agreement state broad scope licensee or issued by master material license permit or issued by a master material license permittee of broad scope between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).~~ 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 ~~radioactive~~ byproduct material on a license issued by ~~the agency,~~ 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 ~~January 1, 2003~~ 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 ~~radioactive~~ byproduct material issued by ~~the agency,~~ 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 ~~between January 1, 2003, and May 3, 2006~~ 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.

ITEM 52. Amend subrules 41.2(77) and 41.2(78) as follows:

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 ~~as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78)"b." (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's web page.)~~ 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) to (4) No change.

b. Has completed 700 hours in a structured education program consisting of both:

(1) No change.

(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 ~~by-product~~ 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)"a"(1), (2), and (3), or 41.2(78)"b"(1)~~ 41.2(78)*"b"* and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

ITEM 53. Amend subrules 41.2(81) and 41.2(82) as follows:

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 ~~agency,~~ NRC~~,~~ or an agreement state ~~and who meets the requirements in 41.2(81)*"c"*(3)~~. ~~(~~The names of the ~~specialty boards~~ board certifications that have been recognized by the ~~agency,~~ NRC~~,~~ or agreement state ~~must be~~ 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 ~~has achieved a level of competency sufficient to function~~ 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 ~~written~~ attestation must be ~~signed by a~~ 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~~. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have~~ 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 agency, NRC, or agreement state, and who meets the requirements in 41.2(82)*"c"*(3). (The names of the specialty boards board certifications that have been recognized by the agency, 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 has achieved a level of competency sufficient to function 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 ~~written~~ attestation must be ~~signed by a~~ 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~~. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have~~ 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).

ITEM 54. Amend subrule 41.2(85) as follows:

41.2(85) ~~*Decay of strontium-90*~~ *Strontium-90 sources for ophthalmic treatment.*

~~*a.* Only an authorized medical physicist shall 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).~~

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.

~~*b.*~~ *c.* A licensee shall retain a record of the activity of each strontium-90 source ~~in accordance with 41.2(84).~~ 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.

ITEM 55. Amend subrule 41.2(87) as follows:

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 ~~by-product~~ byproduct material or any therapeutic dose of radiation from ~~by-product~~ 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 ~~either~~ sodium iodide ~~I-125 or~~ I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide ~~I-125 or~~ 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 ~~radioisotope~~ radionuclide, treatment site, dose per fraction, number of fractions and total dose; ~~or~~

(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

~~(6)~~ (7) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the ~~radioisotope~~ radionuclide, ~~number of sources, and source strengths~~ and dose; and

2. After implantation but prior to completion of the procedure: the ~~radioisotope~~ radionuclide, treatment site, number of sources, ~~and~~ total source strength and exposure time (or, equivalently, the total dose), and date;

~~(7)~~ (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. ~~Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.~~ 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.

~~*g.*~~ *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 ~~by-product~~ 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 ~~with~~ within 48 hours of the oral revision.

~~*h.*~~ *i.* A copy of the written directive in auditable form shall be retained for three years after the date of administration.

ITEM 56. Amend subrule 41.2(89) as follows:

41.2(89) *Training for the parenteral administration of unsealed ~~by-product~~ 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:

~~*a.*~~ (1) Is an authorized user under 41.2(69) for parenteral administration ~~of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required~~ uses listed in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

~~*b.*~~ (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)*"d"*~~ 41.2(89)*"b"*; or

~~*c.*~~ (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)*"d"*~~ 41.2(89)*"b"*; or

~~*d.*~~ *b.* The physician:

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations~~, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~radioactive~~ byproduct material;
5. Using procedures to contain spilled ~~radioactive~~ 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 ~~for which a written directive is required, of either any beta emitter~~

~~or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required~~ 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 ~~*"c,"*~~ (2), and ~~has achieved a level of competency sufficient to function~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed ~~by-product~~ byproduct material requiring a written directive. The ~~written~~ attestation must be ~~signed by a~~ 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 ~~of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.~~ 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).

ITEM 57. Amend **641—Chapter 45**, title, as follows:

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS, PARTICLE ACCELERATORS FOR NONHUMAN USE, ANALYTICAL X-RAY EQUIPMENT, AND WELL-LOGGING

ITEM 58. Amend paragraph **45.1(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 16, 2018~~ July 22, 2020.

ITEM 59. Amend subrule 45.1(18) as follows:

45.1(18) ~~*Notification of incidents*~~ *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.

[Filed 5/14/20, effective 7/22/20]
[Published 6/17/20]
EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5060C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to teleconference options for official meetings

The Public Health Department hereby amends Chapter 55, "Advisory Council on Brain Injuries," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 135.22A(7) and 2019 Iowa Acts, House File 766, section 80.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 135.22A(7) and 2019 Iowa Acts, House File 766, section 80.

Purpose and Summary

2019 Iowa Acts, House File 766, section 80, requires the Department of Public Health to provide for a teleconference option for any board, commission, committee or council member to participate in official meetings. The first of these amendments removes paragraph 55.6(1)"b," which requires quarterly meetings of the Advisory Council on Brain Injuries to be held in a specific month. This allows more meeting scheduling flexibility within the quarter to address the scheduling needs of the members. The amendments also remove the requirement for appointed members to participate in meetings in person unless there are extenuating circumstances; affirm that a teleconference option shall be set up for members; and remove subrule 55.6(12) related to electronic meetings that is no longer necessary.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 25, 2020, as **ARC 4999C**. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 13, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver and variance provisions contained in 641—Chapter 178.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 55.6(1) as follows:

55.6(1) The council shall meet at least quarterly.

~~*a.*~~ The annual meeting schedule shall be established by the beginning of the fiscal year.

~~*b.* Meetings will be held the following months: January, April, July and October.~~

ITEM 2. Amend subrule 55.6(10) as follows:

55.6(10) Meeting attendance.

a. Council members are expected to ~~be present in person for~~ 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. ~~If there are extenuating circumstances, a~~ A teleconference ~~may~~ option shall be set up for the ~~member~~ members to participate in the ~~business portion of the~~ meeting.

d. Appointed members may be recommended for dismissal from the council if they miss more than three meetings annually.

ITEM 3. Rescind subrule **55.6(12)**.

[Filed 5/14/20, effective 7/22/20]
[Published 6/17/20]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5061C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rule making related to spouses of active duty service members

The Public Health Department hereby amends Chapter 196, "Military Service and Veteran Reciprocity," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 272C.4.

PUBLIC HEALTH DEPARTMENT[641](cont'd)

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 272C.4.

Purpose and Summary

2019 Iowa Acts, House File 288, amended Iowa Code section 272C.4, which governs the duties of boards for establishing procedures to expedite the licensing of individuals who are veterans or actively serving in the military. This change in the Iowa Code directs the Department to establish procedures to expedite the licensing of spouses of active duty members of the military forces in cases in which the spouse is already licensed in another state where the professional and occupational licensing requirements are substantially equivalent to Iowa's requirements. The amendments meet the requirements of 2019 Iowa Acts, House File 288.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 25, 2020, as **ARC 5000C**. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the State Board of Health on May 13, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's waiver and variance provisions contained in 641—Chapter 178.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend **641—Chapter 196**, title, as follows:

MILITARY SERVICE, ~~AND~~ VETERAN RECIPROCITY, AND SPOUSES OF ACTIVE DUTY SERVICE MEMBERS

ITEM 2. Amend rule 641—196.1(85GA,ch1116), parenthetical implementation statute, as follows:

641—196.1(~~85GA,ch1116~~ 272C) Definitions.

ITEM 3. Adopt the following **new** definition of "Spouse" in rule **641—196.1(85GA,ch1116)**:

"Spouse" means a spouse of an active duty member of the military forces of the United States.

ITEM 4. Amend rule 641—196.2(85GA,ch1116), parenthetical implementation statute, as follows:

641—196.2(~~85GA,ch1116~~ 272C) Military education, training, and service credit.

ITEM 5. Amend rule 641—196.3(85GA,ch1116) as follows:

641—196.3(~~85GA,ch1116~~ 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 ~~veteran~~ 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 ~~veteran~~ 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 ~~a veteran~~ an applicant has not passed the required examination(s) for licensure, the ~~veteran~~ 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 ~~veteran~~ 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 ~~veteran~~ applicant in connection with a contested case conducted pursuant to this subrule.

ITEM 6. Amend **641—Chapter 196**, implementation sentence, as follows:

These rules are intended to implement ~~2014 Iowa Acts, chapter 1116, section 34~~ Iowa Code section 272C.4.

[Filed 5/14/20, effective 7/22/20]
[Published 6/17/20]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/17/20.

ARC 5062C

VETERINARY MEDICINE BOARD[811]

Adopted and Filed

Rule making related to prohibition of licensing sanctions for student loan default or delinquency

The Board of Veterinary Medicine hereby amends Chapter 5, "Public Records and Fair Information Practices," Chapter 6, "Application for Veterinary Licensure," and Chapter 10, "Discipline," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 169.5.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 169.

Purpose and Summary

This rule making prohibits the suspension or revocation of 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.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on March 25, 2020, as **ARC 5013C**. A public hearing was held on April 15, 2020, at 8 a.m. via telephone.

No one attended the public hearing. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on May 22, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 22, 2020.

The following rule-making actions are adopted:

ITEM 1. Rescind and reserve rule **811—5.18(17A,22,169,261)**.

ITEM 2. Rescind and reserve rule **811—6.8(169,261)**.

ITEM 3. Amend **811—Chapter 6**, implementation sentence, as follows:

These rules are intended to implement Iowa Code chapters 17A~~,~~ and 169~~, and 261~~.

ITEM 4. Rescind subparagraph **10.6(1)"b"(22)**.

ITEM 5. Renumber subparagraph **10.6(1)"b"(23)** as **10.6(1)"b"(22)**.

ITEM 6. Adopt the following **new** paragraph **10.6(1)"c"**:

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.

[Filed 5/29/20, effective 7/22/20]
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PUBLIC HEARINGS: POSSIBLE USE OF TELEPHONIC OR ELECTRONIC FORMAT DUE TO COVID-19

To protect public health and promote efficient government operations during the COVID-19 outbreak, the format of a public hearing on a notice of intended action (NOIA) scheduled and published in the Iowa Administrative Bulletin (IAB) may be changed, without further publication in the IAB, from an in-person hearing at a physical location to a hearing conducted solely via telephonic or electronic means. For information on whether the format of a public hearing as published in the IAB has changed and how to participate telephonically or electronically in such a hearing, see the Internet site of the relevant agency or contact the agency directly using the contact information published in the NOIA. See also section 139 of the Governor's proclamation of disaster emergency issued May 26, 2020: governor.iowa.gov/sites/default/files/documents/Public%20Health%20Proclamation%20-%202020.05.26%20%281%29.pdf.

CORRECTION TO EFFECTIVE DATE OF ARC 5045C

ARC 5045C, an Adopted and Filed rule making to amend Chapter 15 of the Iowa Insurance Division's administrative rules, was published in the Iowa Administrative Bulletin (IAB) on June 3, 2020. The Iowa Insurance Division provides this informational notice to correct the erroneous effective date of July 8, 2020, that was published in the preamble of **ARC 5045C**. The correct effective date for **ARC 5045C** is January 1, 2021. This January 1, 2021, date is the effective date that was adopted by the Iowa Insurance Commissioner on May 11, 2020. The Iowa Administrative Code will be corrected accordingly.