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

In addition to the changes adopted by agencies, the replacement pages may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(4); an effective date delay imposed by the ARRC pursuant to section 17A.4(5) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(6); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index and for the preliminary sections of the IAC: General Information about the IAC, Chapter 17A of the Code of Iowa, Style and Format of Rules, Table of Rules Implementing Statutes, and Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in the first column below correspond to the divider tabs in the IAC binders. Obsolete pages of the IAC are listed in the "Remove Old Pages" column. New and replacement pages included in this Supplement are listed in the "Insert New Pages" column. Carefully remove and insert pages as directed.

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UPDATING INSTRUCTIONS
April 5, 2000, Biweekly Supplement
[Previous Supplement dated 3/22/00]

	Remove Old Pages*	Insert New Pages
EDUCATION DEPARTMENT[281]	Ch 6, p. 9—Ch 6, p. 12	Ch 6, p. 9—Ch 6, p. 13
	Ch 63, p. 5—Ch 63, p. 7	Ch 63, p. 5—Ch 63, p. 7
Educational Examiners Board[282]	Ch 11, p. 1, 2	Ch 11, p. 1, 2
	Ch 11, p. 13, 14	Ch 11, p. 13, 14
HUMAN SERVICES DEPARTMENT[441]	Analysis, p. 3, 4	Analysis, p. 3, 4
	Analysis, p. 7, 8	Analysis, p. 7, 8
	Ch 25, p. 21	Ch 25, p. 21—Ch 25, p. 24
	Ch 41, p. 33, 34	Ch 41, p. 33, 34
	Ch 41, p. 47, 48	Ch 41, p. 47, 48
	Ch 53, p. 1—Ch 53, p. 5	Ch 53, p. 1—Ch 53, p. 4
	Ch 65, p. 21, 22	Ch 65, p. 21, 22
	Ch 65, p. 29, 30	Ch 65, p. 29, 30
	Ch 75, p. 78a	Ch 75, p. 78a
	Ch 75, p. 91, 92	Ch 75, p. 91, 92
	Ch 114, p. 1, 2	Ch 114, p. 1, 2
	Ch 114, p. 17	Ch 114, p. 17
	Ch 152, p. 7—Ch 152, p. 10	Ch 152, p. 7—Ch 152, p. 10
	Ch 185, p. 37, 38	Ch 185, p. 37, 38
	Ch 185, p. 61, 62	Ch 185, p. 61, 62
Racing and Gaming Commission[491]	Ch 1, p. 3—Ch 1, p. 6	Ch 1, p. 3—Ch 1, p. 6
Natural Resource Commission[571]	Analysis, p. 5, 6	Analysis, p. 5, 6
	Ch 34, p. 1—Ch 34, p. 3	Ch 34, p. 1—Ch 34, p. 3

*These pages may be archived for tracing the history of a rule.

	Remove Old Pages*	Insert New Pages
PUBLIC HEALTH DEPARTMENT[641]	Analysis, p. 5, 6	Analysis, p. 5, 6
	Ch 38, p. 1—Ch 39, p. 4	Ch 38, p. 1—Ch 39, p. 4
	Do not remove p. 4a	
	Ch 39, p. 15—Ch 39, p. 22	Ch 39, p. 15—Ch 39, p. 22
	Ch 39, p. 35—Ch 40, p. 4	Ch 39, p. 35—Ch 40, p. 4
	Ch 40, p. 7, 8	Ch 40, p. 7, 8
	Ch 40, p. 11, 12	Ch 40, p. 11, 12
	Ch 40, p. 16c, 16d	Ch 40, p. 16c, 16d
	Ch 40, p. 19, 20	Ch 40, p. 19, 20
	Ch 40, p. 103—Ch 41, p. 12	Ch 40, p. 103—Ch 41, p. 12
	Ch 41, p. 15, 16	Ch 41, p. 15, 16
	Ch 41, p. 19—Ch 41, p. 22	Ch 41, p. 19—Ch 41, p. 22
	Ch 41, p. 33, 34	Ch 41, p. 33, 34
	Ch 41, p. 49—Ch 41, p. 52	Ch 41, p. 49—Ch 41, p. 52
	Ch 41, p. 57—Ch 41, p. 62	Ch 41, p. 57—Ch 41, p. 62
	Ch 41, p. 65, 66	Ch 41, p. 65, 66
	Ch 41, p. 73—Ch 41, p. 104	Ch 41, p. 73—Ch 41, p. 112
	Ch 42, p. 3—Ch 42, p. 6	Ch 42, p. 3—Ch 42, p. 6
	Ch 42, p. 9, 10	Ch 42, p. 9, 10
	Ch 45, p. 1—Ch 45, p. 10	Ch 45, p. 1—Ch 45, p. 10
	Ch 45, p. 15—Ch 45, p. 22	Ch 45, p. 15—Ch 45, p. 22
	Ch 45, p. 25, 26	Ch 45, p. 25, 26
	Ch 45, p. 41—Ch 46, p. 4	Ch 45, p. 41—Ch 46, p. 4
	Ch 46, p. 13	Ch 46, p. 13
Nursing Board[655]	Analysis, p. 1, 2	Analysis, p. 1, 2
	Ch 2, p. 1, 2	Ch 2, p. 1, 2
	Ch 2, p. 9—Ch 2, p. 11	Ch 2, p. 9—Ch 2, p. 11
TRANSPORTATION DEPARTMENT[761]	Analysis, p. 11, 12	Analysis, p. 11, 12
	Ch 452, p. 1	Ch 452, p. 1
Workforce Development Board/Services Division[877]	Ch 2, p. 1—Ch 2, p. 3	Ch 2, p. 1—Ch 2, p. 3
Index Volume	"D" Tab, p. 1-35	"D" Tab, p. 1-34

*These pages may be archived for tracing the history of a rule.

6.14(8) Disclosure of prohibited communications. A presiding officer who receives a prohibited ex parte communication during the pendency of a contested case must initially determine if the effect of the communication is so prejudicial that the presiding officer should be disqualified. If the presiding officer determines that disqualification is warranted, a copy of any prohibited written communication, all written responses to the communication, a written summary stating the substance of any prohibited oral or other communication not available in written form for disclosure, all responses made, and the identity of each person from whom the presiding officer received a prohibited ex parte communication shall be submitted for inclusion in the record under seal by protective order or disclosed. If the presiding officer determines that disqualification is not warranted, such documents shall be submitted for inclusion in the record and served on all parties. Any party desiring to rebut the prohibited communication must be allowed the opportunity to do so upon written request filed within ten days after notice of the communication.

6.14(9) Promptly after being assigned to serve as presiding officer at any stage in a contested case proceeding, a presiding officer shall disclose to all parties material factual information received through ex parte communication prior to such assignment unless the factual information has already been or shortly will be disclosed pursuant to Iowa Code section 17A.13(2) or through discovery. Factual information contained in an investigative report or similar document need not be separately disclosed by the presiding officer as long as such documents have been or will shortly be provided to the parties.

6.14(10) The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule including default, a decision against the offending party, censure, or suspension or revocation of the privilege to practice before the agency. Violation of ex parte communication prohibitions by agency personnel shall be reported to the legal consultant for the department of education for possible sanctions including censure, suspension, dismissal, or other disciplinary action.

281—6.15(17A) Record.

6.15(1) Upon the request of any party, oral proceedings in whole or in part shall be either transcribed, if recorded by certified shorthand reporters, or copied if recorded by mechanical means, with the expense for the transcription of copies charged to the requesting party.

6.15(2) All recordings, stenographic notes or transcriptions of oral proceedings shall be maintained and preserved by the department for at least five years from the date of a decision.

6.15(3) The record of a hearing under these rules shall include:

a. All pleadings, motions and intermediate rulings.
b. All evidence received or considered and all other submissions.
c. A statement of matters officially noticed.
d. All questions and offers of proof, objections, and rulings thereon.
e. All proposed findings of fact and conclusions of law.
f. Any decision, opinion or report by the administrative law judge presented at the hearing.

281—6.16(17A) Recording costs. Upon request, the department of education shall provide a copy of the whole or any portion of the record at cost. The cost of preparing a copy of the record or of transcribing the hearing record shall be paid by the requesting party.

Parties who request that a hearing be recorded by certified shorthand reporters rather than by electronic means shall bear the cost of that recordation, unless otherwise provided by law.

281—6.17(290,17A) Decision and review.

6.17(1) The presiding officer, after due consideration of the record and the arguments presented, and with the advice and counsel of the staff members, shall make a decision on the appeal. Unless the parties are eligible to and agree to waive their right to a written decision approved by the director or state board of education pursuant to subrule 6.17(7), the proposed decision shall be mailed to the parties or their representatives by regular mail.

6.17(2) The decision shall be based on the laws of the United States, the state of Iowa and the regulations and policies of the department of education and shall be in the best interest of education.

6.17(3) The decision of the presiding officer shall be placed on the agenda of the next regular board meeting for review of the record and decision unless the decision is issued orally at hearing under subrule 6.17(7) or unless the decision is within the province of the director to make.

6.17(4) Any adversely affected party may appeal a proposed decision to the state board within 20 days after the date of the proposed decision.

6.17(5) An appeal of a proposed decision is initiated by filing a timely notice of appeal with the office of the director. The notice of appeal must be signed by the appealing party or a representative of that party and contain a certificate of service. The notice shall specify:

a. The names and addresses of the parties initiating the appeal;

b. The proposed decision to be appealed;

c. The specific findings or conclusions to which exception is taken and any other exceptions to the decision;

d. The relief sought; and

e. The grounds for relief.

6.17(6) Unless otherwise ordered, within 15 days of the party's filing of the notice of appeal, each appealing party may file exceptions and briefs. Within 10 days after the filing of exceptions and briefs by the appealing party, any party may file a responsive brief. Briefs shall cite any applicable legal authority and specify relevant portions of the record in that proceeding. An opportunity for oral arguments may be given with the consent of the board. Written requests to present oral argument shall be filed with the briefs.

6.17(7) The board may affirm, modify, or vacate the decision, or may direct a rehearing before the director or the director's designee.

6.17(8) Copies of the final decision shall be sent to the parties or their representatives by regular mail within five days after state board action, if required, on the proposed decision.

6.17(9) No individual who participates in the making of any decision shall have advocated in connection with the hearing, the specific controversy underlying the case, or other pending factually related matters. Nor shall any individual who participates in the making of any proposed decision be subject to the authority, direction, or discretion of any person who has advocated in connection with the hearing, the specific controversy underlying the hearing, or a pending related matter involving the same parties.

6.17(10) In an appeal from the denial of a parent's or guardian's request for open enrollment, where the denial was for missing the deadline for filing for open enrollment without good cause for being late, the parties to the appeal may request that the presiding officer issue an oral decision on the merits of the case at the conclusion of the hearing. An agreement by the parties to waive their right to a written decision reviewed by the director or state board in favor of an oral decision after the hearing may be rescinded by either party if a request is submitted in writing and mailed or delivered in person to the presiding officer with 30 days following the hearing. A written decision will not be expedited but will be issued at a later date in sequence with other written decisions in the order in which the case was heard.

A request to waive a written decision shall not be granted by the presiding officer if the issue in the case is an issue of first impression or is not substantially similar to the issue decided by the state board or director which serves as precedent to the presiding officer.

281—6.18(290) Finality of decision. The decision is final upon board approval of the presiding officer's decision.

281—6.19(17A) Default.

6.19(1) If a party fails to appear or participate in a contested case proceeding after proper service of notice, the presiding officer may, if no adjournment is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party.

6.19(2) Where appropriate and not contrary to law, any party may move for default against a party who has requested the contested case proceeding and has failed to file a required pleading or has failed to appear after proper service.

6.19(3) Default decisions or decisions rendered on the merits after a party has failed to appear or participate in a contested case proceeding become final agency action unless, within 15 days after the date of notification or mailing of the decision, a motion to vacate is filed and served on all parties or an appeal of a decision on the merits is timely initiated within the time provided. A motion to vacate must state all facts relied upon by the moving party which establish that good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated must be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) must be attached to the motion.

6.19(4) The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate.

6.19(5) Properly substantiated and timely filed motions to vacate shall be granted only for good cause shown. The burden of proof as to good cause is on the moving party. Adverse parties shall have ten days to respond to a motion to vacate. Adverse parties shall be allowed to conduct discovery as to the issue of good cause and to present evidence on the issue prior to a decision on the motion, if a request to do so is included in that party's response.

6.19(6) "Good cause" for purposes of this rule shall have the same meaning as "good cause" for setting aside a default judgment under Iowa Rule of Civil Procedure 236.

6.19(7) A decision denying a motion to vacate is subject to further appeal within the time limit allowed for further appeal of a decision on the merits in the contested case proceeding.

6.19(8) If a motion to vacate is granted and no timely interlocutory appeal has been taken, the presiding officer shall issue another notice of hearing and the contested case shall proceed accordingly.

6.19(9) A default decision may award any relief consistent with the request for relief made in the petition and embraced in its issues but, unless the defaulting party has appeared, it cannot exceed the relief demanded.

6.19(10) A default decision may provide either that the default decision is to be stayed pending a timely motion to vacate or that the default decision is to take effect immediately.

281—6.20(17A) Application for rehearing of final decision. Any party may file an application for rehearing with the presiding officer stating the specific grounds therefor, and the relief sought, within 20 days after the issuance of any final decision by the board. A copy of the application shall be timely mailed by the department to all parties of record not joining therein. Such application for rehearing shall be deemed to have been denied unless the board or the presiding officer grants the application within 20 days of the filing. A rehearing shall not be granted unless it is necessary to correct a mistake of law or fact, or for other good cause.

281—6.21(17A) Rehearing.

6.21(1) In the event a rehearing is granted, the presiding officer, in arriving at a subsequent decision, may either review the record and arguments or may proceed with either a full or partial hearing under the appeal hearing provisions of this chapter.

6.21(2) Following the rehearing, the presiding officer shall place the proposed decision on the agenda of the next regular board meeting for review of the record and decision as provided for in 6.17(290,17A).

281—6.22(17A) Emergency adjudicative proceedings.

6.22(1) *Necessary emergency action.* To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare and, consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order. Before issuing an emergency adjudicative order the department shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

b. Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

c. Whether the person required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

e. Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

6.22(2) *Issuance of order.*

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action.

b. The written emergency adjudicative order shall be immediately delivered to persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal delivery;

(2) Certified mail, return receipt requested, to the last address on file with the department;

(3) Certified mail to the last address on file with the department;

(4) First-class mail to the last address on file with the department; or

(5) Fax. Fax may be used as the sole method of delivery if the person required to comply with the order has filed a written request that department orders be sent by fax and has provided a fax number for that purpose.

c. To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

6.22(3) *Oral notice.* Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the persons who are required to comply with the order.

6.22(4) *Completion of proceedings.* After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

Issuance of a written emergency adjudicative order shall include notification of the date on which departmental proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further agency proceedings to a later date will be granted only in compelling circumstances upon application in writing.

These rules are intended to implement Iowa Code sections 256.7(6), 275.16, 282.18, 282.18(5), 282.32, 285.12, and Iowa Code chapter 290 and chapter 17A as amended by 1998 Iowa Acts, chapter 1202.

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[Filed 4/13/99, Notice 3/10/99—published 5/5/99, effective 6/9/99]
[Filed emergency 3/17/00—published 4/5/00, effective 3/17/00]

281—63.15(282) Aides. Educational aides shall be provided preservice and in-service opportunities consistent with duties to be performed and shall work under the direct supervision of the teacher.

281—63.16(282) Accounting. Revenues, expenditures, and balances of the juvenile home programs shall be accounted for in the manner provided in Uniform Financial Accounting for Iowa LEAs and AEAs, except as otherwise noted in these rules.

63.16(1) *Fund.* Juvenile home instructional programs shall be accounted for in a special revenue fund. The fund balances shall be maintained in the special revenue fund at year end, and the continuance or disposition of positive or negative fund balances shall be determined by the department of education.

63.16(2) *Tuition.* Tuition paid or received shall be calculated as follows:

a. If juvenile home students not requiring special education attend a local school district, other than the district of residence, tuition shall be calculated in the manner prescribed in Iowa Code section 282.24 for determining tuition costs for any nonresident student attending a local school district. In lieu of paying tuition to the local school district for these students, the AEA may request the local school district to account for these students through the foster care facility claim process.

b. Tuition for students provided a special education program pursuant to an IEP shall be paid by the district of residence, in accordance with the rules of special education and pursuant to Iowa Code chapter 282, to the district in which the juvenile home is located or to the AEA, whichever is providing the special education. The district in which the juvenile home is located or the AEA, whichever is providing the special education, shall notify the district of residence if the child was being served on the third Friday in September by the district in which the home is located or by the AEA. The district in which the juvenile home is located or the AEA, whichever is providing the special education, shall also notify the district of residence if the child was being served on December 1 by the district in which the home is located or by the AEA.

281—63.17(282) Revenues. Revenues shall include:

1. Funding received pursuant to Iowa Code section 282.31,
2. Educational excellence funding received pursuant to Iowa Code chapter 294A for teachers in the juvenile home program,
3. Tuition revenue from the district of residence or agency in another state for educational services provided for out-of-state students,
4. Tuition revenue from the district of residence for educational services for students provided a special education program pursuant to an IEP, and
5. Other miscellaneous funding received or accrued for the purpose of operating the juvenile home instructional programs.

281—63.18(282) Expenditures. Expenditures may include actual instructional expenditures, student support services expenditures, instructional staff support services expenditures, administrative support services, operations and maintenance of plant services, student transportation services, and interfund transfers for indirect costs. Supplies and equipment necessary to provide the educational program shall be equivalent to those provided to a comparable number of students by the district in which the juvenile home is located. Classroom space shall be adequate for the number and needs of children in the juvenile home instructional program.

63.18(1) *Instructional expenditures.* Instructional expenditures may include:

a. Salaries and employee benefits of employees providing instructional services. Included are teachers, substitutes, other instructional personnel, and aides.

b. Purchased services, supplies, and equipment, which are customarily considered instructional expenditures.

c. Intrafund transfers.

d. The department of education shall annually determine the maximum amount that may be expended on instructional expenditures. Total expenditures for instructional services for each continuing classroom, other than salary and employee benefits, which are not provided pursuant to an IEP shall not exceed 10 percent of the state average expenditure on instructional salaries and employee benefits in the juvenile home program in the year prior to the base year. New classrooms in the first year of operation shall not exceed twice the maximum amount calculated.

63.18(2) *Student and instructional staff support services and student transportation services expenditures.* Among the services included in these categories are guidance services, transportation services, curriculum development, library and instructional technology. Expenditures may include salaries, employee benefits, purchased services, supplies, equipment, and intrafund transfers.

63.18(3) *Administrative support services, operation and maintenance of plant services, and interfund transfers.* Administrative support services, operation and maintenance of plant services and interfund transfer expenditures may include:

a. Intrafund transfers and actual costs of general administration services provided to the juvenile home program. Expenditures for general administrative costs shall correspond to the amount of the administrator's time assigned and provided to the juvenile home program.

b. Intrafund transfers and actual costs of division administrative services provided to the juvenile home program. Expenditures for division administrative costs shall correspond to the amount of the administrator's time assigned and provided to the juvenile home program.

c. Expenditures for the administrative services of administrative staff assigned directly to the juvenile home program.

d. Expenditures for business administration services provided to the juvenile home program. The juvenile home program may be charged for costs of providing business administration services. If the juvenile home program is charged for providing business administration services, the amount shall be either actual costs or the amount determined by using the restricted indirect cost rate applied to allowable juvenile home program expenditures.

e. The total of all expenditures for administrative services shall be no greater than the actual cost determined by the AEA's accounting records or 10 percent of the total expenditures in the juvenile home program, whichever is less.

f. Expenditures for operation and maintenance of plant services except as restricted in subrule 63.18(4).

g. The total of all expenditures for administrative services and for operation and maintenance of plant services shall be no greater than the actual cost determined by the AEA's cost accounting system or 20 percent of the total expenditures in the juvenile home program, whichever is less.

***63.18(4)** *Unauthorized expenditures.* Expenditures shall not include expenditures for debt services, for facilities acquisition and construction services including remodeling and facility repair, or for rental expenditures for classroom facilities when adequate space is available at the juvenile home or AEA.

63.18(5) *Charges for AEA services.* As required by rules 63.7(282), 63.8(282), and 63.9(282), juvenile home students shall have available to them special education support services, educational services, and media services comparable to those services made available to other students in the AEA; however, expenditures for these services are inherent costs to the respective AEA programs and are not to be assessed to the juvenile home educational program.

*Effective date of 3/15/00 delayed 70 days by the Administrative Rules Review Committee at its meeting held March 10, 2000.

281—63.19(282) Claims. AEAs shall submit program and budget proposals and claims consolidating all juvenile home education programs within each AEA. Certain program information may be required for each separate juvenile home.

The number of classrooms being provided by each AEA shall be reported on the budget proposals and claims. The number is to be expressed in terms of full-time equivalent (FTE) classrooms. One FTE represents a full-time teacher providing a program during the normal school year. One-tenth FTE shall be added for each month of summer school taught on a daily full-time basis. A full school year and three months of summer school is calculated as 1.3 FTE.

Pursuant to Iowa Code section 294.4, each teacher shall keep a daily register which shall include the name, age, attendance, and enrollment status of each student.

The average daily membership of students of school age living in juvenile homes who are being provided an educational program shall be reported on the budget proposals and claims. *"Average daily membership (ADM)"* shall mean the average obtained by dividing the total of the aggregate days of attendance plus the aggregate days of absence by the total number of student contact days. Student contact days are the days during which the educational program is provided and students are under the guidance and instruction of the instructional professional staff. *"Aggregate days"* means the sum of the number of days of attendance and days of absence for all pupils who are enrolled during the school year. A student shall be considered enrolled after being placed in a juvenile home and taking part in the educational program. A student is considered to be in membership from the date of enrollment until the date of leaving the juvenile home or receiving a high school diploma or its equivalent, whichever occurs first. ADM shall be calculated on the regular school year exclusive of summer session. School age is defined pursuant to Iowa Code chapter 282.

281—63.20(282) Audits. AEAs must make the records related to providing educational services for juvenile homes available to independent auditors, state auditors and department of education staff on request.

281—63.21(282) Waivers. A waiver may be requested by an AEA which presents evidence of a need for a different configuration of expenditures under paragraph 63.18(1)*"d,"* 63.18(3)*"a,"* 63.18(3)*"b,"* 63.18(3)*"e,"* or 63.18(3)*"g,"* or subrule 63.18(4) or 63.18(5). The AEA must annually request the waiver and must include the waiver request and the evidence required by this rule with the program and budget proposal or budget amendment submitted pursuant to rule 63.3(282) or rule 63.4(282). An approved waiver related to rent payment to the juvenile home does not require an annual waiver request except in any year that the rental contract terms change from the rental contract terms in the previous year.

If the department denies a waiver request, the AEA which was denied may request within ten days of notification of the denial that the director of the department of education review the denial of the waiver request.

It is the intent of the department of education to waive requirements only when it is determined that they would result in unequal treatment of the AEAs or cause an undue hardship to the requesting AEA and the waiver clearly is in the public interest.

These rules are intended to implement Iowa Code sections 282.30 and 282.31.

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*Effective date of 63.18(4) delayed 70 days by the Administrative Rules Review Committee at its meeting held March 10, 2000.

CHAPTER 11*
COMPLAINTS, INVESTIGATIONS, CONTESTED CASE HEARINGS

[Prior to 6/15/88, see Professional Teaching Practices Commission[640] Ch 2]
[Prior to 5/16/90, see Professional Teaching Practices Commission[287] Ch 2]

282—11.1(17A,272) Scope and applicability. This chapter applies to contested case proceedings conducted by the board of educational examiners.

282—11.2(17A) Definitions. Except where otherwise specifically defined by law:

"Board" means the board of educational examiners.

"Complainant" means any qualified party who files a complaint with the board.

"Contested case" means a proceeding defined by Iowa Code section 17A.2(5) and includes any matter defined as a no factual dispute contested case under 1998 Iowa Acts, chapter 1202, section 14.

"Issuance" means the date of mailing of a decision or order or date of delivery if service is by other means unless another date is specified in the order.

"Party" means each person or agency named or admitted as a party or properly seeking and entitled as of right to be admitted as a party.

"Presiding officer" means an administrative law judge from the Iowa department of inspections and appeals or the full board or a three-member panel of the board.

"Proposed decision" means the presiding officer's recommended findings of fact, conclusions of law, decision, and order in a contested case in which the full board did not preside.

"Respondent" means any individual who is charged in a complaint with violating the criteria of professional practices or the criteria of competent performance.

282—11.3(17A,272) Jurisdictional requirements.

11.3(1) The case must relate to alleged violation of the criteria of professional practices or the criteria of competent performance.

11.3(2) The magnitude of the alleged violation must be adequate to warrant a hearing by the board.

11.3(3) There must be sufficient evidence to support the complaint.

11.3(4) As an additional factor, it should appear that a reasonable effort has been made to resolve the problem on the local level. However, the absence of such an effort shall not preclude investigation by the board.

282—11.4(17A,272) Complaint.

11.4(1) *Who may initiate.*

a. Licensed practitioners employed by a school district or their educational entity or their recognized local or state professional organization.

b. Local boards of education.

c. Parents or guardians of students involved in the alleged complaint.

11.4(2) *Form and content of the complaint.*

a. The complaint shall be in writing and signed by at least one complainant or an authorized representative if the complainant is an organization. (An official form may be used. This form may be obtained from the board upon request.)

b. The complaint shall show venue as "BEFORE THE BOARD OF EDUCATIONAL EXAMINERS" and shall be captioned "COMPLAINT".

*Effective date of March 15, 2000, delayed 45 days by the Administrative Rules Review Committee at its meeting held March 10, 2000.

c. The complaint shall contain the following information:

(1) The full name, address and telephone number of the complainant.

(2) The full name, address and telephone number, if known, of the respondent.

(3) A concise statement of the facts which clearly and accurately apprises the respondent of the alleged violation of the criteria of professional practices or the criteria of competent performance and shall state relief sought by the complainant.

11.4(3) *Required copies—place and time of filing.*

a. In addition to the original, a sufficient number of copies of the complaint must be filed to enable service of one copy to each of the respondents and retention of 12 copies for use by the board.

b. The complaint must be delivered personally or by mail to the office of the board. The current office address is the Grimes State Office Building, Third Floor, Des Moines, Iowa 50319.

c. Timely filing is required in order to ensure the availability of witnesses and to avoid initiation of an investigation under conditions which may have been significantly altered during the period of delay.

11.4(4) *Service of complaint.* The board or a designee of the board shall serve a copy of the complaint upon the respondent by one of the following means:

a. Personal service as provided in the Iowa Rules of Civil Procedure; or

b. Certified mail, return receipt requested; or

c. First-class mail; or

d. Publication, as provided in the Iowa Rules of Civil Procedure.

11.4(5) *Amendment or withdrawal of complaint.* A complaint or any specification thereof may be amended or withdrawn by the complainant at any time prior to notification of the respondent, and thereafter at the sole discretion of the board.

11.4(6) *Voluntary surrender of license.* When a formal complaint has been filed under Iowa Code chapter 272 and rule 11.4(17A,272), the respondent may voluntarily surrender the license by admitting the truth of the allegations of the complaint and completing a waiver of hearing form provided by the board. The surrender shall result in the permanent revocation of the respondent's license.

11.4(7) *Investigation of license reports.*

a. Reports received by the board from another state, territory or other jurisdiction concerning licenses or certificate revocation or suspension shall be reviewed and investigated by the board in the same manner as is prescribed in these rules for the review and investigation of written complaints.

b. Failure to report a license revocation, suspension or other disciplinary action taken by licensing authority of another state, territory or jurisdiction within 30 days of the final action by such licensing authority shall constitute cause for initiation of an investigation.

282—11.5(272) Investigation of complaints. The chairperson of the board or the chairperson's designee may assign an investigation of a complaint to a member of the board or may request an investigator to investigate the complaint or report. The investigating board member or investigator may consult an assistant attorney general concerning the investigation or evidence produced from the investigation. Upon completion of the investigation, the investigating board member or investigator shall prepare a report of the investigation for consideration by the board in determining whether probable cause exists. A board member who has personally investigated a complaint is disqualified from participating in any contested case proceeding resulting from the investigation.

282—11.6(272) Ruling on the initial inquiry. Upon review of the investigator's report, the board may take any of the following actions:

11.6(1) *Reject the case.* If a determination is made by the board to reject the case, the complaint shall be returned to the complainant along with a statement specifying the reasons for rejection. A letter of explanation concerning the decision of the board shall be sent to the respondent.

282—11.29(17A,272) Applications for rehearing.

11.29(1) *By whom filed.* Any party to a contested case proceeding may file an application for rehearing from a final order.

11.29(2) *Content of application.* The application for rehearing shall state on whose behalf it is filed, the specific grounds for rehearing, and the relief sought. In addition, the application shall state whether the applicant desires reconsideration of all or part of the board decision on the existing record and whether, on the basis of the grounds enumerated in subrule 11.28(4), the applicant requests an opportunity to submit additional evidence.

11.29(3) *Time of filing.* The application shall be filed with the board within 20 days after issuance of the final decision.

11.29(4) *Notice to other parties.* A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein. If the application does not contain a certificate of service, the board shall serve copies on all parties.

11.29(5) *Disposition.* Any application for a rehearing shall be deemed denied unless the board grants the application within 20 days after its filing.

282—11.30(17A,272) Stays of board actions.

11.30(1) *When available.*

a. Any party to a contested case proceeding may petition the board for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board. The petition shall be filed with the notice of appeal and shall state the reasons justifying a stay or other temporary remedy. The executive director may rule on the stay or authorize the presiding officer to do so.

b. Any party to a contested case proceeding may petition the board for a stay or other temporary remedies pending judicial review of all or part of that proceeding. The petition shall state the reasons justifying a stay or other temporary remedy.

11.30(2) *When granted.* In determining whether to grant a stay, the executive director or presiding officer shall consider the factors listed in 1998 Iowa Acts, chapter 1202, section 23(5c).

11.30(3) *Vacation.* A stay may be vacated by the issuing authority upon application of the board or any other party.

282—11.31(17A,272) No factual dispute contested cases. If the parties agree that no dispute of material fact exists as to a matter that would be a contested case if such a dispute of fact existed, the parties may present all relevant admissible evidence either by stipulation or otherwise as agreed by the parties, without necessity for the production of evidence at an evidentiary hearing. If such agreement is reached, a jointly submitted schedule detailing the method and timetable for submission of the record, briefs and oral argument should be submitted to the presiding officer for approval as soon as practicable. If the parties cannot agree, any party may file and serve a motion for summary judgment pursuant to the rules governing such motions.

282—11.32(17A,272) Emergency adjudicative proceedings.

11.32(1) *Necessary emergency action.* To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the board may issue a written order in compliance with Iowa Code section 17A.18 to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the board by emergency adjudicative order. Before issuing an emergency adjudicative order the board shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the board is proceeding on the basis of reliable information;

b. Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

c. Whether the person required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

e. Whether the specific action contemplated by the board is necessary to avoid the immediate danger.

11.32(2) *Issuance of order.*

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the board's decision to take immediate action.

b. The written emergency adjudicative order shall be immediately delivered to persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal delivery;

(2) Certified mail, return receipt requested, to the last address on file with the board;

(3) Certified mail to the last address on file with the board;

(4) First-class mail to the last address on file with the board; or

(5) Fax. Fax may be used as the sole method of delivery if the person required to comply with the order has filed a written request that board orders be sent by fax and has provided a fax number for that purpose.

c. To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

11.32(3) *Oral notice.* Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the board shall make reasonable immediate efforts to contact by telephone the persons who are required to comply with the order.

11.32(4) *Completion of proceedings.* After the issuance of an emergency adjudicative order, the board shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

Issuance of a written emergency adjudicative order shall include notification of the date on which board proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further board proceedings to a later date will be granted only in compelling circumstances upon application in writing.

These rules are intended to implement Iowa Code chapter 17A as amended by 1998 Iowa Acts, chapter 1202, and chapter 272.

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CHAPTER 25
DISABILITY SERVICES MANAGEMENT

DIVISION I
DETERMINATION OF STATE PAYMENT AMOUNT

25.1(331) Definitions
25.2(331) Eligibility conditions
25.3(331) County expenditure reports
25.4(331) State payment calculation report
25.5 to 25.10 Reserved

DIVISION II
COUNTY MANAGEMENT PLAN

25.11(331) Definitions
25.12(331) County management plan—general criteria
25.13(331) Policies and procedures manual
25.14(331) Policies and procedures manual review
25.15(331) Amendments
25.16(331) Reconsideration
25.17(331) Management plan annual review
25.18(331) Strategic plan
25.19(331) Technical assistance
25.20 to 25.40 Reserved

DIVISION III
MINIMUM DATA SET

25.41(331) Minimum data set
25.42 to 25.50 Reserved

DIVISION IV
INCENTIVE AND EFFICIENCY POOL FUNDING

25.51(77GA,HF2545) Desired results areas
25.52(77GA,HF2545) Methodology for applying for incentive funding
25.53(77GA,HF2545) Methodology for awarding incentive funding
25.54(77GA,HF2545) Subsequent year performance factors
25.55(77GA,HF2545) Phase-in provisions
25.56 to 25.60 Reserved

DIVISION V
RISK POOL FUNDING

25.61(426B) Definitions
25.62(426B) Risk pool board
25.63(426B) Application process
25.64(426B) Methodology for awarding risk pool funding
25.65(426B) Repayment provisions
25.66(426B) Appeals

CHAPTERS 26 and 27
Reserved

CHAPTER 28
POLICIES FOR ALL INSTITUTIONS

28.1(218) Definitions
28.2(218) Voluntary admissions to mental health institute
28.3(218) Admission to hospital-schools
28.4(229) Patients' rights for the mentally ill
28.5(218) Photographing and recording of patients and use of cameras
28.6(218) Interviews and statements
28.7(218) Use of grounds, facilities, or equipment
28.8(218) Tours of institution
28.9(218) Donations
28.10(218) Residents' rights for the mentally retarded
28.11(218) Catchment areas
28.12(217) Release of confidential information

CHAPTER 29
MENTAL HEALTH INSTITUTES

29.1(218) Visiting
29.2(230) Direct medical services
29.3(230) Liability for support

CHAPTER 30
STATE HOSPITAL-SCHOOLS

30.1(218) Visiting
30.2(222) Liability for support

CHAPTER 47
PILOT DIVERSION INITIATIVES

DIVISION I
PILOT FIP-APPLICANT DIVERSION PROGRAM

47.1(239B) Definitions
47.2(239B) Availability of program
47.3(239B) General criteria
47.4(239B) Assistance available
47.5(239B) Relationship to the family investment program and TANF
47.6(239B) Local plans
47.7(239B) Notification and appeals
47.8(239B) Funding, rates and method of payment
47.9(239B) Termination of pilot projects
47.10(239B) Records and reports
47.11(239B) Renewal of existing approved pilot projects
47.12 to 47.20 Reserved

DIVISION II
FAMILY SELF-SUFFICIENCY GRANTS PROGRAM

47.21(239B) Definitions
47.22(239B) Availability of the family self-sufficiency grants program
47.23(239B) General criteria
47.24(239B) Assistance available in family self-sufficiency grants
47.25(239B) Application, notification, and appeals
47.26(239B) Approved local plans for family self-sufficiency grants
47.27 to 47.40 Reserved

DIVISION III
PILOT COMMUNITY SELF-SUFFICIENCY GRANTS PROGRAM

47.41(239B) Definitions
47.42(239B) Availability of the community self-sufficiency grants program
47.43(239B) General criteria
47.44(239B) Assistance available under community self-sufficiency grants
47.45(239B) Approved pilot project plans
47.46(239B) Notification and appeals for community self-sufficiency grant projects
47.47(239B) Termination of pilot projects
47.48(239B) Records and reports
47.49(239B) Renewal of existing approved pilot projects
47.50 to 47.60 Reserved

DIVISION IV
PILOT POST-FIP DIVERSION PROGRAM

47.61(239B) Definitions
47.62(239B) Submitting proposals
47.63(239B) Project administration
47.64(239B) Availability of program
47.65(239B) General criteria
47.66(239B) Assistance available
47.67(239B) Local plans
47.68(239B) Notification and appeals
47.69(239B) Funding, rates and method of payment
47.70(239B) Termination of pilot projects
47.71(239B) Records and reports
47.72(239B) Renewal of existing approved pilot projects

CHAPTER 48
FAMILY INVESTMENT PROGRAM ELIGIBILITY UNDER SELF-EMPLOYMENT DEMONSTRATION PROJECTS

DIVISION I

48.1 to 48.20 Reserved

DIVISION II
FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

48.21(249C) Pilot project site selection criteria
48.22(249C) Program area
48.23(249C) Family investment program eligibility

CHAPTER 49
TRANSITIONAL CHILD CARE ASSISTANCE PROGRAM

DIVISION I

49.1 to 49.20 Reserved

DIVISION II
FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

49.21(239B) Eligibility for transitional child care
49.22(239B) Eligible children
49.23(239B) Child care facilities eligible to participate
49.24(239B) Effective date of eligibility
49.25(239B) Reasons for ineligibility for transitional child care assistance
49.26(239B) Income
49.27(239B) Copayments

441—25.53(77GA,HF2545) Methodology for awarding incentive funding. Each county shall report on all performance measures listed in this division, plus any additional performance measures the county has selected, by December 1 of each year.

25.53(1) *Reporting.* Each county shall report performance measure information on forms, or by electronic means, developed for the purpose by the department in consultation with the state county management committee.

25.53(2) *Scoring.* The department shall analyze each county's report to determine the extent to which the county achieved the levels contained in the proposal accepted by the state county management committee. Prior to distribution of incentive funding to counties, results of the analysis shall be shared with the state county management committee.

25.53(3) *County ineligibility.* A county which does not report performance measure data by December 1 will be ineligible to receive incentive funds for that fiscal year. A county may apply for an extension by petitioning the state county management committee prior to December 1. The petition shall describe the circumstances which will cause the report to be delayed and identify the date by which the report will be submitted.

441—25.54(77GA,HF2545) Subsequent year performance factors. For any fiscal year which begins after July 1, 1999, the state county management committee shall not apply any additional performance measures until the county management information system (CoMIS) developed and maintained by the division of mental health and developmental disabilities has been modified, if necessary, to collect and calculate required data elements and performance measures and each county has been given the opportunity to establish baseline measures for those measures.

441—25.55(77GA,HF2545) Phase-in provisions.

25.55(1) *State fiscal year 1999.* For the fiscal year which begins July 1, 1998, each county shall collect data as required above in order to establish a baseline level on all performance measures. A county which collects and reports all required data by December 1, 1999, shall be deemed to have received a 100 percent score on the county's performance indicators.

25.55(2) *State fiscal year 2000.* A county which submits a proposal with its management plan for the fiscal year which begins July 1, 1999, and reports the levels achieved on the selected performance measures by December 1, 2000, shall be deemed to have received a 100 percent score on the county's performance indicators, regardless of the actual levels achieved.

These rules are intended to implement 1998 Iowa Acts, House File 2545, section 8, subsection 2.

441—25.56 to **25.60** Reserved.

DIVISION V
RISK POOL FUNDING

PREAMBLE

441—25.61(426B) Definitions.

"Aggregate application" means the request for funding when a county has an unanticipated cost for mental health, mental retardation, and developmental disabilities services fund expenditures that would result in the county's current fiscal year budget exceeding the sum of 105 percent of the county's current fiscal year budget amount and the county's prior fiscal year accrual ending fund balance exceeding 25 percent of the prior fiscal year gross services fund expenditures.

"Available pool" means those funds remaining in the risk pool less any actuarial and other direct administrative costs.

"Commission" means the mental health and developmental disabilities commission.

"Division" means the mental health and developmental disabilities division of the department of human services.

"Individual application" means the request for funding when a county has individuals who have unanticipated disability conditions with an exceptional cost and the individuals are either new to the county's service system or the individuals' disability conditions have changed or are new.

"Loan" means the risk pool funds a county received in a fiscal year in which the county did not levy the maximum amount allowed for the county's mental health, mental retardation, and developmental disabilities services fund under Iowa Code section 331.424A.

441—25.62(426B) Risk pool board. This nine-member board consists of two county supervisors, two county auditors, a member of the state-county management committee created in Iowa Code section 331.438 who was not appointed by the Iowa state association of counties, a member of the county finance committee created in Iowa Code chapter 333A who is not an elected official, and two single entry point process administrators, all appointed by the governor, subject to confirmation by two-thirds of the members of the senate, and one member appointed by the director of the department of human services.

25.62(1) *Organization.*

a. The members of the board shall annually elect from the board's voting membership a chairperson and vice-chairperson of the board.

b. Members appointed by the governor shall serve three-year terms.

25.62(2) *Duties and powers of the board.* The board's powers and duties are to make policy and to provide direction for the administration of the risk pool established by Iowa Code section 426B.5, subsection 3. In carrying out these duties, the board shall do all of the following:

a. Recommend to the commission for adoption rules governing the risk pool fund.

b. Determine application requirements to ensure prudent use of risk pool assistance.

c. Accept or reject applications for assistance in whole or in part.

d. Review the fiscal year-end financial records for all counties that are granted risk pool assistance and determine if repayment is required.

e. Approve actuarial and other direct administrative costs to be paid from the pool.

25.62(3) *Board action.*

a. A quorum shall consist of two-thirds of the membership appointed and qualified to vote.

b. When a quorum is present, an action is carried by a majority of the qualified members of the board.

25.62(4) *Board minutes.*

a. Copies of administrative rules and other materials considered are made part of the minutes by reference.

b. Copies of the minutes are kept on file in the office of the administrator of the division of mental health and developmental disabilities.

25.62(5) *Board meetings.*

a. The board shall meet in April of each year and may hold special meetings at the call of the chairperson or at the request of a majority of the voting members.

b. Any county making application for risk pool funds must be present at the board meeting where that request will be considered. The division shall notify the county of the date, time and location of the meeting. Any other persons with questions about the date, time or location of the meeting may contact the Administrator, Division of Mental Health and Developmental Disabilities, Department of Human Services, Hoover State Office Building, Fifth Floor, 1305 East Walnut, Des Moines, Iowa 50309-0114, telephone (515)281-5874.

c. The board shall comply with applicable provisions of Iowa's open meetings law, Iowa Code chapter 21.

25.62(6) *Records.* Any records maintained by the board or on behalf of the board shall be made available to the public for examination in compliance with Iowa's open records law, Iowa Code chapter 22. To the extent possible, prior to submitting applications, records and documents, applicants shall delete any confidential information. These records shall be maintained in the office of the division of mental health and developmental disabilities.

25.62(7) *Conflict of interest.* A board member cannot be a part of any presentation to the board of that board member's county's application for risk pool funds nor can the board member be a part of any action pertaining to that application.

25.62(8) *Robert's Rules of Order.* In cases not covered by these rules, Robert's Rules of Order shall govern.

441—25.63(426B) Application process.

25.63(1) *Who may apply.* A county may make an aggregate or individual application at any time on or before April 1 of any given year for the current fiscal year budget whenever the projected need exceeds the sum of 105 percent of the county's current fiscal year budget amount and the county's prior fiscal year accrual ending fund balance exceeds 25 percent of the prior fiscal year gross services fund expenditures.

The purpose of the mental health risk pool is to assist counties whose expenditures in the mental health, mental retardation, and developmental disabilities services fund exceed budgeted costs due to unanticipated expenses for new individuals or other unexpected factors. The mental health risk pool is not intended for multiyear usage or as a source of planned revenue.

25.63(2) *How to apply.* The county shall send Form 470-3723, Risk Pool Application, plus 15 copies, to the division. The division must receive the application no later than 4:30 p.m. on April 1 of each year; or, if April 1 is a holiday, a Saturday or Sunday, the division must receive the application no later than 4:30 p.m. on the first working day following. Facsimiles and electronic mail are not acceptable. The application shall be signed and dated by both the chairperson of the county board of supervisors and the central point of coordination administrator. Staff of the division shall notify each county of receipt of the county's application.

The county shall attach the following forms to the application:

a. Form 634A, Revenues Detail.

b. Form 634B, Service Area Detail (pages 1 to 10).

c. Form 634C, Service Area 4 Supporting Detail (pages 1 to 8).

d. Form 638R, Statement of Revenues, Expenditures, and Changes in Fund Balance—Actual and Budget (2 pages).

e. If the budget has been amended, Form 653A-R, Record of Hearing and Determination on the Amendment to County Budget (sheet 2), for both the current fiscal year budget, as last amended, and the prior fiscal year gross services fund expenditures.

25.63(3) *Request for additional information.* Staff shall review all applications for completeness. If an application is not complete, staff of the division shall contact the county within four working days after April 1 or the first working day thereafter, if April 1 is a holiday, a Saturday or Sunday, and request the information needed to complete the application. The county shall submit the required information within five working days from the date of the division's request for the additional information.

441—25.64(426B) Methodology for awarding risk pool funding.

25.64(1) *Notice of decision.* The risk pool board shall notify the chair of the applying county's board of supervisors of the board's action. Copies shall be sent to the county auditor and the central point of coordination administrator.

25.64(2) *Distribution of funds.* The total amount of the risk pool shall be limited to the available pool for a fiscal year. If the total dollar amount of the approved applications exceeds the available pool, the board shall prorate the amount paid for an approved application. The funds will be prorated to each county based upon the proportion each approved county's request is of the total amount of all approved requests.

441—25.65(426B) Repayment provisions.

25.65(1) *Required repayment.* Counties shall be required to repay risk pool funds in the following situations:

a. A loan was granted to the county because the county did not levy the maximum amount allowed for the county's mental health, mental retardation, and developmental disabilities services fund under Iowa Code section 331.424A. The county shall be required to repay the risk pool loan funds in the succeeding fiscal year.

b. The county had levied the maximum amount allowed for the county's mental health, mental retardation, and developmental disabilities services fund, but the county's actual need for risk pool assistance was less than the amount of risk pool assistance granted to the county. The county shall refund the difference between the amount of assistance granted and the actual need.

25.65(2) *Year-end report.* Each county granted risk pool funds shall complete a year-end financial report. The division shall review the accrual information and notify the mental health risk pool board if any county that was granted assistance in the prior year received more than the county's actual need based on the submitted financial report.

25.65(3) *Notification to county.* The chairperson of the mental health risk pool board shall notify each county by January 1 of each fiscal year of the amount to be reimbursed. The county shall reimburse the risk pool within 30 days of receipt of notification by the chairperson of the mental health risk pool board. If a county fails to reimburse the mental health risk pool, the board may request a revenue offset through the department of revenue and finance. Copies of the overpayment and request for reimbursement shall be sent to the county auditor and the central point of coordination administrator of the county.

441—25.66(426B) Appeals. The risk pool board may accept or reject an application for assistance from the risk pool fund in whole or in part. The decision of the board is final and is not appealable.

These rules are intended to implement Iowa Code section 426B.5, subsection 3.

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CHAPTER 26
COUNTY MAINTENANCE OF EFFORT CALCULATIONS AND REPORTING
Rescinded IAB 5/5/99, effective 7/1/99

CHAPTER 27
Reserved

ac. Payments received from the comprehensive child development program, funded by the Administration for Children, Youth, and Families, provided the payments are considered complimentary assistance by federal regulation.

ad. Incentive allowance payments received from the work force investment project, provided the payments are considered complimentary assistance by federal regulation.

ae. Interest and dividend income.

af. Rescinded IAB 12/3/97, effective 2/1/98.

ag. Terminated income of recipient households who are subject to retrospective budgeting beginning with the calendar month the source of the income is absent, provided the absence of the income is timely reported as described at 441—subrule 40.24(1) and 441—subparagraph 40.27(4)*"f"*(1).

EXCEPTION: Income that terminated in one of the two initial months occurring at time of an initial application that was not used prospectively shall be considered retrospectively as required by 41.27(9)*"b"*(1). If income terminated and is timely reported but a grant adjustment cannot be made effective the first of the next month, a payment adjustment shall be made. This subrule shall not apply to nonrecurring lump sum income defined at 41.27(9)*"c"*(2).

ah. Welfare reform and regular household honorarium income. All moneys paid to a FIP household in connection with the welfare reform demonstration longitudinal study or focus groups shall be exempted.

ai. Diversion or self-sufficiency grants assistance as described at 441—Chapter 47.

aj. Payments from property sold under an installment contract as specified in paragraphs 41.26(4)*"b"* and 41.27(1)*"f."*

ak. All census earnings received by temporary workers from the Bureau of the Census for Census 2000 during the period of April 1, 2000, through January 31, 2001.

41.27(8) *Treatment of income in excluded parent cases, stepparent cases, and underage parent cases.*

a. Treatment of income in excluded parent cases.

(1) Treatment of income when the parent is a citizen or an alien other than those described in 41.23(4)*"a"*(3). A parent who is living in the home with the eligible child(ren) but whose needs are excluded from the eligible group is eligible for the 20 percent earned income deduction, the 50 percent work incentive deduction described at 41.27(2)*"a"* and *"c,"* and diversions described at 41.27(4), and shall be permitted to retain that part of the parent's income to meet the parent's needs as determined by the difference between the needs of the eligible group with the parent included and the needs of the eligible group with the parent excluded except as described at 41.27(11). All remaining nonexempt income of the parent shall be applied against the needs of the eligible group.

(2) Treatment of income of a parent who is ineligible because of lawful temporary or permanent resident status. The income of a parent who is ineligible as described in 41.23(4)*"a"*(3) shall be attributable to the eligible group in the same manner as the income of a stepparent is determined pursuant to 41.27(8)*"b"*(1) to (7), (9) and (10). Nonrecurring lump sum income received by the parent shall be treated in accordance with 41.27(9)*"c"*(2).

b. Treatment of income in stepparent cases. The income of a stepparent who is not included in the eligible group, but is living with the parent in the home of the eligible child(ren), shall be given the same consideration and treatment as that of a natural parent subject to the limitations of subparagraphs (1) to (10) below.

(1) The stepparent's monthly gross nonexempt earned income, earned as an employee or monthly net profit from self-employment, shall receive a 20 percent earned income deduction.

(2) Rescinded IAB 6/30/99, effective 7/1/99.

(3) Any amounts actually paid by the stepparent to individuals not living in the home, who are claimed or could be claimed by the stepparent as dependents for federal income tax purposes, shall be deducted from nonexempt monthly earned and unearned income of the stepparent.

(4) The stepparent shall also be allowed a deduction from nonexempt monthly earned and unearned income for alimony and child support payments made to individuals not living in the home with the stepparent.

(5) Except as described at 41.27(11), the nonexempt monthly earned and unearned income of the stepparent remaining after application of the deductions in 41.27(8)*"b"*(1) to (4) above shall be used to meet the needs of the stepparent and the stepparent's dependents living in the home, when the dependents' needs are not included in the eligible group and the stepparent claims or could claim the dependents for federal income tax purposes. These needs shall be determined in accordance with the family investment program standard of need for a family group of the same composition.

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CHAPTER 53
RENT SUBSIDY PROGRAM

PREAMBLE

This chapter defines and structures the rent subsidy program for persons who participate in a home- and community-based service (HCBS) waiver program and who were:

1. Discharged from a medical institution in which they have resided,
2. At risk of institutional placement, or
3. Able to leave a medical institution by use of services provided under an HCBS waiver upon turning 18 years of age during the last year of their institutional stay.

This program is designed to provide rent assistance to these persons to help them live successfully in their own home and community. An eligible person may receive assistance in meeting rental expense and, in the initial two months of eligibility, in purchasing necessary household furnishings and supplies.

441—53.1(78GA,ch203) Definitions.

"Adult" means a person aged 18 or over.

"Department" means the Iowa department of human services.

"Division" means the division of mental health and developmental disabilities of the department of human services.

"Home-and community-based waiver program" means any of the waiver programs administered by the department under the provisions set forth in 441—Chapter 83 including, but not limited to, the ill and handicapped waiver, the elderly waiver, the AIDS/HIV waiver, the mental retardation waiver, the brain injury waiver, and the physical disabilities waiver.

"Intermediate care facility for the mentally retarded (ICF/MR)" means an institution that is primarily for the diagnosis, treatment, or rehabilitation of persons who are mentally retarded and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination and integration of health or related services to help each individual function at the greatest ability and is an approved Medicaid vendor.

"Medical institution" means an ICF/MR, nursing facility, skilled nursing facility, or hospital that is an approved Medicaid provider.

441—53.2(78GA,ch203) Eligibility requirements. All of the following criteria shall be met.

53.2(1) *HCBS recipient.* The person shall be an adult recipient of one of the home- and community-based services waiver programs.

53.2(2) *Discharged from a medical institution.* Except as provided in subrules 53.2(4) and 53.2(5), the person shall have been discharged from a medical institution on or after July 1, 1995, and immediately prior to receiving HCBS services.

53.2(3) *Demonstrated need.* To demonstrate need, applicants must provide evidence that they are responsible for paying more than 30 percent of their income for rent and that they are not receiving and are ineligible for other rental assistance. This program may not be used to substitute for any other subsidy that a person had been receiving at the time of or prior to the time of application to this program. Persons receiving rental assistance at the time of or prior to the time of application to this program shall not be eligible.

53.2(4) *Risk of institutional placement.* Up to 100 persons who can avoid placement in a medical institution by accessing this rent subsidy program and by use of services provided under an HCBS waiver shall be eligible for rental assistance. Applicants must meet all eligibility criteria of this program, except the requirements of subrule 53.2(2), and be able to demonstrate both of the following:

a. That they have insufficient funds to pay their community housing costs and that insufficient funds will cause them to enter a medical institution.

b. That participating in an HCBS waiver will prevent them from entering a medical institution and that access to this rental subsidy program is required so that they may live in a community living arrangement permitted under a waiver.

53.2(5) *Turning 18 years of age.* In lieu of meeting the criteria in subrule 53.2(2) or 53.2(4) above, rent subsidy funds may be made available to persons who are able to leave a medical institution by use of services provided under an HCBS waiver who turn 18 years of age during the last year of their institutional stay.

53.2(6) *Ineligible for other rent subsidies.* The person shall have been determined ineligible or be on the waiting list for rent subsidy programs under the U.S. Department of Housing and Urban Development (HUD) or any other available rent subsidy programs.

53.2(7) *Responsible for rent.* The person shall be financially responsible for rent or housing costs.

441—53.3(78GA,ch203) Application. Applications for the rent subsidy program may be obtained at any county office of the department. Applications shall be submitted to the Department of Human Services, Division of Mental Health and Developmental Disabilities, Hoover State Office Building, Des Moines, Iowa 50319-0114.

53.3(1) *Application process.* A person who wishes to apply shall complete Form 470-3302, Application for HCBS Rent Subsidy and Household Assistance, and provide verification of the following:

a. The person's estimated monthly income for the 12 months following application, including written evidence from the income sources used to determine that income.

b. Written evidence from sources of local rental assistance available in the applicant's community that the applicant has applied for that rental assistance and that the applicant has been determined ineligible or placed on a waiting list for that rental assistance.

c. The amount of the person's rent payment.

d. The amount of assistance needed for purchase of needed household furnishings and supplies.

53.3(2) *Date of application.* The date of the application shall be the date the application, including written verification of income and written verification of application to other rental assistance programs, is received by the division of mental health and developmental disabilities.

53.3(3) *Eligibility determination.* The person or the person's legal guardian shall be notified within 15 working days of the date of application of the department's eligibility determination. The notice shall state the date payments shall begin, the amount of monthly payments and, if different, the amount of the first two payments.

53.3(4) *Waiting list.* After funds appropriated for this purpose are obligated, pending applications shall be denied by the division.

a. A denial shall require a notice of decision to be mailed within 15 working days. The notice shall state that the applicant meets eligibility requirements but no funds are available and that the applicant shall be placed on the waiting list, or that the applicant does not meet eligibility requirements.

b. Applicants not awarded funding who meet the eligibility requirements shall be placed on a statewide waiting list according to the order in which the completed applications and verification were received by the division. In the event that more than one application is received at one time, the person shall be entered on the waiting list on the basis of the day of the month of the person's birthday, lowest number being first on the waiting list. Any subsequent tie shall be decided by the month of birth, January being month one and the lowest number.

c. When funding allows additional persons to be added to the rent subsidy program, they shall be taken from the statewide waiting list, and their eligibility shall be redetermined at that time. An application packet, which includes instructions and necessary forms for verification of continuing eligibility, shall be sent to these persons for completion and returned to the division within timelines specified by the department. If the signed application and verification of continuing eligibility are not received by the timeline specified by the department, the person's name shall be dropped from consideration for receipt of the rent subsidy payment.

441—53.4(78GA,ch203) Amount of rent subsidy.

53.4(1) *Use of subsidy.* Except as provided in subrule 53.4(3), assistance shall be used for rental expense.

53.4(2) *Maximum monthly payment for rent.* Assistance for rent shall be equal to the rent paid, not to exceed 110 percent of the maximum prevailing fair market rent under guidelines of the applicable United States Department of Housing and Urban Development (HUD) low-rent housing program in the area where the person's residence is located, less 30 percent of the gross income of the individual consumer. The fair market rent used shall be that for a one-bedroom home or a proportionate share of rental costs in living units containing more than one bedroom.

53.4(3) *Assistance with other purchases.* Assistance may be given in the initial two months of eligibility for purchases necessary for household furnishings and supplies. The maximum available for household furnishings and supplies shall be $500. This shall be a one-time payment and shall be available only to persons leaving a medical institution immediately prior to applying to this program. The maximum amount shall be available to all eligible persons, including those who may have entered this program prior to the time this maximum amount took effect. In these cases, payments may be made retroactively to persons to reconcile the differences.

53.4(4) *Monthly payment.* Consumers approved for rent subsidy payments shall receive an ongoing monthly payment which is equal to the amount determined pursuant to subrule 53.4(2). An approved subsidy shall be payable as of the first of the month following approval. The initial payment will also include any approved payments for prior months.

441—53.5(78GA,ch203) Redetermination of eligibility.

53.5(1) *Time of completion.* A redetermination of eligibility for rent subsidy payments shall be completed:

a. At least once every 12 months.

b. When a change in circumstances occurs that affects eligibility in accordance with rule 441—53.2(78GA,ch203).

c. If the person moves from the residence stated on Form 470-3302.

d. When there is a change in income.

53.5(2) *Review packet.* The division shall send a review packet, which shall include instructions and necessary forms for verification of continuing eligibility, to all recipients of subsidy payments at least 60 calendar days prior to the deadline date for annual redetermination of eligibility. The completed Form 470-3302, Application for HCBS Rent Subsidy and Household Assistance, and required verification materials shall be submitted annually to the Department of Human Services, Division of Mental Health and Developmental Disabilities, Hoover State Office Building, Des Moines, Iowa 50319-0114. If the signed application and verification of continuing eligibility are not received by the division by the thirtieth day following the date the review packet is sent, the person's subsidy shall be terminated.

441—53.6(78GA,ch203) Termination of rent subsidy payments.

53.6(1) *Reasons for termination.* The rent subsidy shall terminate at the end of the month in which any of the following occur and a notice shall be sent which states the reason for the termination:

a. The person does not meet one or more of the eligibility criteria listed in rule 441—53.2(78GA,ch203).

b. The person dies.

c. Completion of the required documentation is not received.

d. No further funds are available for the rent subsidy program.

53.6(2) *Reporting of changes.* The person is required to report to the division within ten working days any changes which may affect eligibility. Failure to do so may result in responsibility for repayment of funds and termination of the subsidy. (See rule 441—53.7(78GA,ch203).)

53.6(3) *Insufficient funding.* If funds are not sufficient to cover payments for all persons on the subsidy, persons shall be terminated from the subsidy in inverse order to the dates they began receiving payments, i.e., the last person to be added to the subsidy being the first person to be removed. The person terminated shall move back to the waiting list with the person's original application date dictating the person's position on the waiting list as stated at subrule 53.3(4). The division is responsible for notifying the persons who will be removed from the subsidy for this reason.

441—53.7(78GA,ch203) Fraudulent practices relating to the rent subsidy program. A person is guilty of a fraudulent practice if that person with the intent to gain financial assistance to which that person is not eligible, knowingly makes or causes to be made a false statement or representation or knowingly fails to report to an employee of the department any change in circumstances affecting that person's eligibility for financial assistance. In cases of found fraudulent practices, the department may require repayment of the amount that was received by the recipient while ineligible as a condition of continued participation in the rent subsidy program.

441—53.8(78GA,ch203) Appeals. The applicant or recipient may appeal a denial of an application or termination of the subsidy payment pursuant to 441—Chapter 7.

These rules are intended to implement Iowa Code section 217.6 and 1999 Iowa Acts, chapter 203, section 11, subsection 3.

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65.29(3) *Exclusion of income from 2000 census employment.* All earnings received by temporary workers from the Bureau of the Census for Census 2000 during the period of April 1, 2000, through January 31, 2001, shall be excluded from income.

65.29(4) *Interest income for retrospectively budgeted cases.* Prorate interest income by dividing the amount anticipated during the certification period by the number of months in the certification period.

65.29(5) *Social security plans for achieving self-support (PASS).* Notwithstanding anything to the contrary in these rules or regulations, exclude income amounts necessary for fulfillment of a plan for achieving self-support (PASS) under Title XVI of the Social Security Act.

65.29(6) *Student income.* Notwithstanding anything to the contrary in these rules or regulations, exclude educational income based on amounts earmarked by the institution, school, program, or other grantor as made available for the specific costs of tuition, mandatory fees, books, supplies, transportation and miscellaneous personal expenses (other than living expenses). If the institution, school, program, or other grantor does not earmark amounts made available for the allowable costs involved, students shall receive an exclusion from educational income for educational assistance verified by the student as used for the allowable costs involved. Students can also verify the allowable costs involved when amounts earmarked are less than amounts that would be excluded by a strict earmarking policy. For the purpose of this rule, mandatory fees include the rental or purchase of equipment, materials and supplies related to the course of study involved.

65.29(7) *Elementary and high school student income.* Notwithstanding anything to the contrary in these rules or regulations, the earnings of elementary or high school students who are members of the household and are 17 years of age or younger shall be excluded.

65.29(8) *Vendor payments.* General assistance vendor payments provided for energy or utility-cost assistance shall also be excluded.

65.29(9) *HUD or FmHA utility reimbursement.* HUD or FMHA utility reimbursement payments shall be excluded from income.

65.29(10) *Welfare reform and regular household honorarium income.* All moneys paid to a food stamp household in connection with the welfare reform demonstration longitudinal study or focus groups shall be exempted.

441—65.30(234) Resources.

65.30(1) *Jointly held resources.* When property is jointly held it shall be assumed that each person owns an equal share unless the intent of the persons holding the property can be otherwise established.

65.30(2) *Exclusion from resource limits.* The value of vehicles necessary to carry fuel for heating or water for home use when the transported fuel or water is the primary source of fuel or water for the household shall be excluded.

65.30(3) *Resources of SSI and FIP household members.* Notwithstanding anything to the contrary in these rules or regulations, all resources of SSI or FIP recipients are excluded. For food stamp purposes, those members' resources, if identified, cannot be included when a household's total resources are calculated.

65.30(4) *Earned income tax credits.* Notwithstanding anything to the contrary in these rules or regulations, earned income tax credits (EITC) shall be excluded from consideration as a resource for 12 months from the date of receipt if the person receiving the EITC was participating in the food stamp program at the time the credits were received, and participated continuously during the 12-month period.

65.30(5) *Vehicles not otherwise excluded.* Notwithstanding anything to the contrary in these rules or regulations, all licensed vehicles not excluded as a resource shall individually be evaluated for fair market value and that portion of the value which exceeds $4,650 shall be attributed in full toward the household's resource level, regardless of any encumbrances on the vehicles.

441—65.31(234) Homeless meal providers. When an office of the department is notified that an establishment or shelter in its administrative area has applied to be able to accept food stamps for homeless persons, staff shall obtain a written statement from the establishment or shelter. The statement must contain information on how often meals are served by the establishment or shelter, the approximate number of meals served per month, and a statement that the establishment or shelter does serve meals to homeless persons. This information must be dated and signed by a person in charge of the administration of the establishment or shelter and give the person's title or function with the establishment.

The establishment or shelter shall cooperate with agency staff in the determination of whether or not meals are served to the homeless.

441—65.32(234) Basis for food stamp allotments. Notwithstanding anything to the contrary in these rules or regulations, the annual adjustment to the maximum allotment shall be based on 100 percent of the Thrifty Food Plan. Allotments shall not fall below the federal fiscal year 1996 level.

441—65.33(234) Maximum monthly dependent care deduction. Notwithstanding anything to the contrary in these rules or regulations, the maximum monthly dependent care deduction households shall be granted is $200 for each child under two years of age and $175 for each other dependent.

441—65.34(234) Exclusion of advance earned income tax credit payments from income. Rescinded IAB 10/30/91, effective 1/1/92.

441—65.35(234) Migrant and seasonal farm worker households. Rescinded IAB 10/30/91, effective 1/1/92.

441—65.36(234) Electronic benefit transfer (EBT) of food stamp benefits.

65.36(1) *Liability for unauthorized use of food stamp EBT benefits.* The department shall not replace EBT benefits that are lost or stolen after being credited to that household's food stamp account unless the loss occurs after the time the household reports the loss, theft, or compromise of their EBT card or PIN to the department or the electronic funds transfer (EFT) network. The food stamp household is liable for unauthorized use of its EBT card that occurs prior to the time the household reports the loss.

65.36(2) *EBT state guarantee.* In the event that the EBT point of sale (POS) system is inoperable, and the household has incurred an expense using a manual voucher against its food stamp account for eligible food items exceeding the balance in their food stamp account, the state shall pay the retailer the balance in that account. In addition, if the balance of the household's food stamp account is less than $40, the state will pay the retailer the difference between $40 and the balance in the account, up to the amount of the purchase, so that the total payment from food stamp benefits and state guarantee does not exceed $40. Payment will not be made for more than one manual voucher transaction for a cardholder at the same retail establishment in one day.

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** Subrules 65.8(11) and 65.108(11) effective 1/1/97.

(2) To qualify for this disregard, the person shall not have earned more than $1,200 in the 12 calendar months prior to the month in which the new job begins, the income must be reported timely in accordance with rule 441—76.10(249A), and the new job must have started after the date the application is filed. For purposes of this policy, the $1,200 earnings limit applies to the gross amount of income without any allowance for exemptions, disregards, work deductions, diversions, or the costs of doing business used in determining net profit from any income test in rule 441—75.57(249A).

(3) If another new job or self-employment enterprise starts while a WTP is in progress, the exemption shall also be applied to earnings from the new source that are received during the original 4-month period, provided that the earnings were less than $1,200 in the 12-month period before the month the other new job or self-employment enterprise begins.

(4) An individual is allowed the 4-month exemption period only once in a 12-month period. An additional 4-month exemption shall not be granted until the month after the previous 12-month period has expired.

(5) If a person whose income is considered enters the household, the new job must start after the date the person enters the home or after the person is reported in the home, whichever is later, in order for that person to qualify for the exemption.

(6) When a person living in the home whose income is not considered subsequently becomes an assistance unit member whose income is considered, the new job must start after the date of the change that causes the person's income to be considered in order for that person to qualify for the exemption.

(7) A person who begins new employment or self-employment that is intermittent in nature may qualify for the WTP. "Intermittent" includes, but is not limited to, working for a temporary agency that places the person in different job assignments on an as-needed or on-call basis, or self-employment from providing child care for one or more families. However, a person is not considered as starting new employment or self-employment each time intermittent employment restarts or changes such as when the same temporary agency places the person in a new assignment or a child care provider acquires another child care client.

ag. Payments from property sold under an installment contract as specified in paragraphs 75.56(4)*"b"* and 75.57(1)*"d."*

ah. All census earnings received by temporary workers from the Bureau of the Census for Census 2000 during the period of April 1, 2000, through January 31, 2001.

75.57(8) *Treatment of income in excluded parent cases, stepparent cases, and underage parent cases.*

a. Treatment of income in excluded parent cases. A parent who is living in the home with the eligible children but whose needs are excluded from the eligible group is eligible for the 20 percent earned income deduction, child care expenses for children in the eligible group, the 50 percent work incentive deduction described at paragraphs 75.57(2)*"a," "b,"* and *"c,"* and diversions described at subrule 75.57(4), and shall be permitted to retain that part of the parent's income to meet the parent's needs as determined by the difference between the needs of the eligible group with the parent included and the needs of the eligible group with the parent excluded except as described at subrule 75.57(10). All remaining nonexempt income of the parent shall be applied against the needs of the eligible group.

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CHAPTER 114
LICENSING AND REGULATION OF ALL GROUP LIVING FOSTER CARE FACILITIES FOR CHILDREN

[Prior to 7/1/83, Social Services[770] Ch 114]
[Prior to 2/11/87, Human Services[498]]

441—114.1(237) Applicability. This chapter outlines the basic standards for all group living foster care facilities and contains the basic standards applicable to community residential facilities for children. Additional standards applicable to specific levels of group living are discussed in 441—Chapter 115, "Licensing and Regulation of Comprehensive Residential Facilities for Children," and 441—Chapter 116, "Licensing and Regulation of Residential Facilities for Mentally Retarded Children."

This rule is intended to implement Iowa Code chapter 237.

441—114.2(237) Definitions.

"Adequate lighting" means a light intensity of 20 foot-candles (approximately equivalent to a 60 watt bulb at a clear distance of 5 feet).

"Caseworker" means any staff of the facility who is primarily responsible for planning for individual children, a family, or groups, as well as coordination with referral sources and coordination of services to the individual.

"Casework supervisor" means any staff of the facility who provides supervision of the caseworker(s) by regularly scheduled face-to-face case specific discussions with the caseworker.

"Chemical restraint" means the use of chemical agents including psychotropic drugs as a form of restraint. The therapeutic use of psychotropic medications as a component of a service plan for a particular child is not considered chemical restraint.

"Child care worker" means any staff of the facility whose primary responsibility is the direct care of children in the facility.

"Community residential facility" means a facility which provides care for children who are considered unable to live in a family situation due to social, emotional or physical disabilities but are capable of interacting in a community environment with a minimum amount of supervision. The facility provides 24-hour care including board and room. Community resources are used for education, recreation, medical, social and rehabilitation services. The facility is responsible for planning the daily activities of the children, discipline, guidance, peer relationships, and recreational programs.

"Control room" means a locked room used for treatment purposes in a comprehensive residential facility.

"Educational degrees" means formally approved certificates from accredited schools.

"Highly structured juvenile program" means a short-term treatment program lasting 90 days and having a high degree of structure that stresses discipline, physical activity, and education.

These programs must be licensed as either community residential facilities under this chapter or as comprehensive residential facilities under 441—Chapter 115 and certified to provide rehabilitative treatment services under 441—Chapter 185. Programs shall have the ability to use a physically secure setting dependent upon the level of the license.

"Locked cottage" means an occupied comprehensive residential facility or an occupied unit of a comprehensive residential facility which is physically restrictive because of the continual locking of doors to prevent the children in care from leaving the facility.

"Mechanical restraint" means restriction by the use of a mechanical device of a child's mobility or ability to use the hands, arms, or legs.

"Physical restraint" means direct physical contact required on the part of a staff member to prevent a child from hurting self, others, or property.

"Prime programming time" means any period of the day when special attention or supervision is necessary, for example, upon awakening in the morning until departure for school, during meals, after school, transition between activities, evenings and bedtime, or weekends and holidays, in order to maintain continuity of program and care. Prime programming time shall be defined by the facility.

"Private juvenile detention home" means a juvenile detention home as defined in Iowa Code section 232.2, which does not meet the requirements of being "county or multicounty" as defined in 441—subrule 105.1(2).

"Private juvenile shelter care home" means a juvenile shelter care home as defined in Iowa Code section 232.2, which does not meet the requirements of being "county or multicounty" as defined in 441—subrule 105.1(2).

"Staff" means any person providing care or services to or on behalf of the facility whether the person is an employee of the facility, an independent contractor or any other person who contracts with the facility, an employee of an independent contractor or any other person who contracts with the facility, or a volunteer.

441—114.3(237) Physical standards. Local building and zoning ordinances shall be met.

114.3(1) *Grounds.*

a. An outdoor play area of 75 square feet per child shall be provided.

b. The play area shall be identified and kept free from hazards that could cause injury to a child.

c. Rubbish and trash shall be kept separated from the play area.

d. The grounds shall be adequately drained.

441—114.21(237) Illness, accident, death, or absence from the facility.

114.21(1) *Notification of illness.* A facility shall notify the child's parent(s), guardian and responsible agency of any serious illness, incident involving serious bodily injury, or circumstances causing removal of the child from the facility.

114.21(2) *Notification of death.* In the event of the death of a child, a facility shall notify immediately the physician, the child's parent(s) or guardian, the placing agency, and the appropriate state authority. The agency shall cooperate in arrangements made for examination, autopsy, and burial.

This rule is intended to implement Iowa Code section 237.2.

441—114.22(237) Records. In the event of closure of a facility, children's records shall be sent to the department of human services for retention according to the records retention policy.

This rule is intended to implement Iowa Code section 237.2.

441—114.23(237) Unannounced visits.

114.23(1) *Time.* The unannounced visit shall occur during periods of the day when the child would normally be in the facility and awake. Visits at other times may occur only as a result of a specific complaint.

114.23(2) *Observations.* The visit shall include an assessment of the following areas:

a. Interaction between the staff and child.

b. Interaction between the children.

c. Discussion with the child about experiences in the facility.

d. A check on any previously sighted deficiencies.

e. Overall impression of the facility.

114.23(3) *Recommendation.* The licensing staff shall recommend follow-up, when needed.

This rule is intended to implement Iowa Code section 237.7.

441—114.24(237) Standards for private juvenile shelter care and detention homes. The standards of 441—Chapter 105 shall be used as the basis for licensing private juvenile shelter care and detention homes. These homes are not required to meet other standards of 441—Chapter 114.

This rule is intended to implement Iowa Code section 237.3.

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441—152.7(234) Restriction of use of funds. The provider shall agree that federally appropriated funds shall not be paid on behalf of the department or provider to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any federal contract, grant, loan or cooperative agreement.

The provider shall ensure that no funds received or expended will be used in any way to promote or oppose unionization.

441—152.8(234) Term of contract. The term of the contract shall be for not more than two years, effective the day following the signature of the director of the department or the director's designee, unless the provider and department agree to a later specified date.

These rules are intended to implement Iowa Code section 234.6.

441—152.9 to **152.20** Reserved.

DIVISION II
PURCHASE OF REHABILITATIVE TREATMENT AND SUPPORTIVE SERVICES CONTRACT
PREAMBLE

This division sets forth the contracting process for providers of rehabilitative treatment and supportive services.

This division addresses how existing family-centered, family preservation, family foster care, and group care providers enter into new contracts to provide rehabilitative treatment and supportive services on or after November 1, 1993; describes how new family-centered, family preservation, family foster care, and group care providers enter into a contract to provide rehabilitative treatment services, nonrehabilitative treatment services, and supportive services on or after January 1, 1994; explains how contracts are administered by department project managers; presents the fiscal records standards; and sets forth the requirements for client eligibility and review organization referral and authorization process as a condition of reimbursement.

441—152.21(234) Contract. All providers of rehabilitative treatment and supportive services shall enter into a contract with the department. Providers may enter into a contract for rehabilitative treatment and supportive services when full certification as described in 441—subrule 185.11(2) is achieved. Certification is not required if the provider is contracting only for supportive services.

441—152.22(234) Initiation of contract proposal.

152.22(1) *Right to request a contract.* All potential providers have a right to request a contract.

152.22(2) *Initial contact.* The initial contact shall be between the potential provider and the regional supervisor of purchase of service for the region in which the provider's headquarters is located. In the case of out-of-state providers this contact can be with the regional supervisor for either the closest region or the region initiating the contact. The "Handbook for Providers of Rehabilitative Treatment and Supportive Services" shall be given to the provider at the beginning of the contract development process. The provider shall sign Form 470-3057, Verification of Receipt, at the end of the contract development process to verify receipt of the "Handbook."

152.22(3) *Contract proposal development.* When the regional supervisor for purchase of service determines that a new contract is to be developed, a project manager shall be assigned to assist in contract development and processing. The project manager shall assist the provider in the completion of the contract proposal and required fiscal information. Form 470-3051, Rehabilitative Treatment and Supportive Services Contract Face Sheet, and Form 470-3404, Rehabilitative Treatment and Supportive Services Negotiated Rate Establishment Attachment, shall be completed at the same time as Form 470-3052, Rehabilitative Treatment and Supportive Services Contract, or Form 470-3053, Amendment of the Rehabilitative Treatment and Supportive Services Contract, is prepared.

152.22(4) *Contract proposal approval.* A proposed contract shall be submitted to the assigned project manager 60 calendar days in advance of the desired effective date of the contract. The Rehabilitative Treatment and Supportive Services Negotiated Rate Establishment Attachment, Form 470-3404, need not be completed until the completion of the rate negotiation process. Contract proposals will not be acted upon until this form is completed and attached to the contract proposal. Submission within the time frame does not ensure the desired effective date of the contract. The applicant shall be given a notice and explanation in writing of delays in the approval process by the department.

The applicant shall submit four copies of the contract proposal to the assigned project manager. The project manager shall forward four signed copies of the contract proposal to the bureau of purchased services within four weeks of receipt.

All complete proposed contracts shall be reviewed for compliance with state and federal requirements by the department. Before the Rehabilitative Treatment and Supportive Services Contract, Form 470-3052, can be effective, it shall be acted upon and signed, if approved, by the following persons within the time frames specified:

a. Authorized representative of the provider agency.

b. Human services area administrator, within one week of receipt.

c. Regional administrator, within one week of receipt.

d. Director of the department of human services or designee, within 15 days of receipt.

Payment cannot be made for services provided prior to the contract effective date.

152.22(5) *Criteria for rejection of contract proposal.* The following criteria may cause a proposed contract or proposed contract amendment to be rejected:

a. The proposed contract does not meet applicable rules, regulations, or guidelines.

b. The applicant has falsified any information required as a condition of participation.

c. Licenses or certification submitted as a condition of participation in the contract process has never been approved, or has been revoked or suspended.

d. The provider fails to provide notification, within seven days, of any changes that may significantly affect the licenses or certification submitted as a condition of contracting.

e. The department and the provider fail to reach agreement on negotiated rates.

The provider shall be given a notice and explanation in writing of the reasons for rejection of the contract proposal by the department within ten working days of the department decision.

152.22(6) *Contract effective date.* When the agreed-upon contract conditions have been met, the effective date of a new contract, a renewed contract or an amendment to add a new service code to the contract is the day following signature of the director of the department or the director's designee, unless the provider and the department agree to a later specified date. A contract can only be effective if signed by all parties as required in subrule 152.22(4).

152.22(7) *Contract expiration date.* The effective date of the contract expiration shall be no more than two years from the effective date of the contract.

441—152.23(234) Contract administration.

152.23(1) *Contract management.* During the contract period, the assigned project manager designated in the contract shall be the contract liaison between the department and the provider. The project manager shall be contacted on all interpretations and problems relating to the contract and shall follow the issues through to their resolution. The project manager shall also monitor performance under the contract and shall provide or arrange for technical assistance to improve the provider's performance if needed. Report of On-Site Visit, Form SS-1715-0, shall be used to monitor performance under the contract. The project manager shall make at least one on-site visit per year to each provider of rehabilitative treatment or supportive services. The on-site visit shall be coordinated with on-site visits scheduled to fulfill requirements for provider audit, licensing, and certification or other on-site visits required by the department. Site visits to out-of-state providers shall be made at the discretion of the region responsible for administration of the contract.

152.23(2) *Contract amendment.*

a. The contract shall be amended only upon agreement of both parties except as provided for in paragraphs 152.23(2)*"b," "c,"* and *"d."* Amendment of the Rehabilitative Treatment and Supportive Services Contract, Form 470-3053, shall be completed by the provider to amend the services being provided, unless the amendment is being processed with a contract renewal. If the amendment is being processed with a contract renewal, the amendment can be indicated on the contract face sheet as a "contract renewal and amendment" and Form 470-3053 does not need to be submitted, as the signature page of the contract renewal can serve as the approval mechanism with authorized signatures. A written explanation of the nature of the amendment shall be attached. Amendments to add a new service must meet the requirements of any licensing or certification required as indicated by issuance of a current certificate of approval. Effective January 1, 1998, the department shall only approve amendments to add a service to an existing contract for which a negotiated rate has been established.

b. Effective August 1, 1998, a contract may be unilaterally amended by the department to delete an existing service if agreement upon a negotiated rate is not reached in accordance with rule 441—185.112(234), except as provided for at 441—subrule 185.112(12). The department shall give the provider 30 days' notice of its intent to amend the rehabilitative treatment and supportive services contract between the provider and the department.

c. A contract may be unilaterally amended by the department to delete an existing service if certification or a required license for that service is revoked, denied or has been voluntarily withdrawn by the provider. The department shall give the provider ten days' notice of its intent to amend the rehabilitative treatment and supportive services contract between the provider and the department.

152.23(3) *Contract renewal.* A joint decision to pursue renewal of the contract shall be made at least 60 days prior to the expiration date. Each contract renewal requires one on-site visit by the project manager and documentation of an evaluation process through the use of Form 470-3054, Contract Renewal Evaluation Guide. The evaluation shall also include the use of other evaluation tools specified in the contract. The results of the evaluation shall be taken into consideration in the department's decision to renew the contract. Site visits to out-of-state providers shall be made at the discretion of the region responsible for administration of the contract.

152.23(4) *Contract termination.*

a. The department may terminate the contract upon ten days' notice for cause except in the event of revocation of licensure, certification or imminent danger to clients, in which case the contract shall be terminated immediately upon notice. The provider or the department may terminate this contract without cause upon 30 days' notice. Notice of termination shall be provided by certified mail.

b. Causes for termination during the period of the contract are:

(1) Determination by the department that insufficient funds are available to continue the services involved.

(2) Failure of the provider to complete or submit required reports.

(3) Failure of the provider to make financial and statistical records available for review by the department or authorized party.

(4) Failure of either party to abide by the provisions of the contract.

(5) Failure to reach agreement on negotiated rates within 130 days of initiating rate negotiations in accordance with rule 441—185.112(234).

c. Within 20 days of any termination made under this clause, the provider shall supply the department with financial statements detailing all costs up to the effective date of termination. The sole and complete remedy of the provider shall be payment for services completed prior to the effective date of termination.

441—152.24(234) Client eligibility and referral.

152.24(1) *Determination of eligibility.* For the department to make payment for rehabilitative treatment services, clients shall be determined eligible by the review organization. Eligibility for non-rehabilitative treatment services shall be determined pursuant to 441—subrule 185.2(4). Eligibility for supportive services shall be determined by the referral worker pursuant to the rules established for the service. The department shall not make payment for rehabilitative treatment or supportive services provided prior to the client's eligibility determination.

152.24(2) *Court order.* If a child and family have been referred to the review organization and the review organization has not authorized rehabilitative treatment services, but the services have been ordered by the juvenile court, the referral worker shall refer the case back to the review organization for reconsideration of eligibility in light of the juvenile court's determination. If the review organization continues not to authorize the services ordered by the juvenile court, the department shall make payment subject to availability of authorized funds.

441—152.25(234) Amount, scope, and duration of services. Any change in the scope, or increase in the amount or duration of rehabilitative treatment services, shall be authorized by the review organization.

441—152.26(234) Client fees. The provider shall agree not to require any fee from departmental clients unless a fee is required by the department and is consistent with federal regulation and state policy.

These rules are intended to implement Iowa Code section 234.6.

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185.83(3) *Enhanced residential treatment.* Enhanced residential treatment provides treatment in a facility licensed under 441—Chapter 115 for children who are unable to live in a family situation due to severe social, emotional or behavioral disabilities and who require a high degree of supervision, structure and treatment services as indicated in the individual treatment plan due to aggressive or other acting-out behavior which may threaten the safety of the individual or the individual's community or family.

Specialized behavior management techniques are used several times per day. In addition, children receiving enhanced residential treatment shall require and receive interventions several times daily to enhance their restorative living and social skills. In addition to the intensive programming and structure, the children are provided with 24-hour awake supervision.

a. Children in enhanced residential treatment shall receive the following services: restorative living or social skills development several times per day and group or individual therapy or counseling. An average of three hours per week of therapy and counseling services shall be provided to each child.

b. During prime programming time, the following ratios of skill development staff to children shall be maintained: 1 staff for facilities serving up to 4 children, 2 for facilities serving 5 to 7 children, 3 for facilities serving 8 to 10 children, 4 for facilities serving 11 to 13 children, 5 for facilities serving 14 to 16 children, 6 for facilities serving 17 to 19 children, and 1 staff for every 3 children for facilities serving 20 or more children. During nonprime programming time, child care staff shall also meet the qualifications for skill development services. During sleeping time, child care staff shall meet the qualifications in 441—paragraph 114.8(1)*"c."*

c. The payment for the daily rate shall be based on a 365-day year.

d. The unit of service for enhanced residential treatment shall be one day.

e. Services shall be provided on a face-to-face basis with the child.

185.83(4) *Highly structured juvenile program.* A highly structured juvenile program must meet the following requirements for licensing, admissions, readmission and discharge, and program and services.

a. Licensing. Facilities shall be licensed under 441—Chapter 114 or 115.

b. Admission criteria. Characteristics of the target population to be served by this program include young men who:

(1) Are aged 15, 16, or 17.

(2) Have been adjudicated delinquent for a public offense that is a serious misdemeanor or above, but is not a forcible felony.

(3) Are not able to benefit further from community-based services at the time of placement, but would be able to successfully return to the community following intensive short-term residential treatment.

Regional administrators for the department, in consultation with juvenile court services, shall have authority to place youth that lack one or more target population characteristics on a case-by-case basis. A regional administrator or designee may delegate this authority to the chief juvenile court officers or their designees. The department and juvenile court services shall keep data on the children placed who lack one or more of the target population characteristics.

c. Readmission and discharge. Program participants may be readmitted to the program for an additional 30, 60, or 90 days. A readmission shall be decided upon and processed in the same manner as the original admission, using the same criteria. A readmission should be a rare occurrence, used only when troublesome behaviors, diagnoses or problems arise late in the original placement, and more time in the program will benefit the child. The department and juvenile court services shall keep data on the children readmitted to the program.

There are no temporary discharges from the highly structured program to detention or other placement for discipline purposes.

d. Program and services. This program is a short-term treatment program with a length of stay of 90 days. Program participants are assembled in cohorts (groups of youth that advance through the program together). Each cohort is a number that is one-third of the program, with a cohort scheduled to finish the 90-day program in 30 days. Discharge planning must be started within the first 30 calendar days of placement.

(1) Youth shall receive restorative living skills development as needed and social skills development several times per day.

(2) One hour of therapy and counseling services shall be provided every week to each youth.

(3) The prime programming time hours and staff-to-client ratio shall meet the treatment and supervision needs of the youth served as specified in 185.10(8)"*c*"(4).

(4) The payment for the daily rate shall be calculated based on a 30-day month. If, however, the department is able to provide payment based on the actual number of days in a month, rates shall be adjusted accordingly.

(5) The unit of service for highly structured juvenile residential treatment shall be one day.

(6) Services shall be provided on a face-to-face basis with the child.

(7) Duration shall not exceed three calendar months.

(8) Youth shall have supervision 24 hours a day by awake staff.

441—185.84(234) Additional services provided in group care. Additional therapy and counseling services to the child that are in excess of frequency and intensity of services set forth in the core group of services and which are approved by the review organization pursuant to rule 441—185.4(234) shall be provided on an individual unit basis. Units of additional therapy and counseling provided in group care shall be defined and reimbursed in half-hour increments, with a billable unit being face-to-face contact with the child. The provider may bill for additional units after documenting that the services are in excess of that required in the daily rate.

441—185.85(234) Duration of services. Group treatment services shall not be authorized for more than six months from the initial day of service provision by the provider. Prior approval shall be obtained from the review organization for services to extend beyond the time period authorized initially.

441—185.86(234) Desired outcomes of group treatment. Desired outcomes are to achieve or document movement toward the goals identified in the permanency plan, treatment plan, or court order, continue engagement in an active school program or employment, reduce or eliminate risk of delinquency of the child, eliminate risk of abuse of the child by the family, and movement to less restrictive level of care (e.g., family, family foster care, independent living).

These rules are intended to implement Iowa Code section 234.38.

441—185.87 to **185.100** Reserved.

DIVISION VII
BILLING AND PAYMENT PROCEDURES

441—185.121(234) Billing procedures. At the end of each month the provider agency shall prepare Form AA–2241–0, Purchase of Service Provider Invoice, for contractual services provided by the agency during the month.

Separate invoices shall be prepared for each county from which clients were referred and each program. Complete invoices shall be sent to the department county office responsible for the client for approval and forwarding for payment.

Providers shall never bill for more than one month of service. A separate invoice is required for each separate month of service, even if the service span overlaps one month.

185.121(1) *Time limit for submitting invoices.* The time limit for submission of original invoices shall be 90 days from the date of service, except at the end of the state fiscal year when claims for services through June 30 are to be submitted by August 10.

185.121(2) *Resubmittals of rejected claims.* Valid claims which were originally submitted within the time limit specified in 185.121(1) but were rejected because of an error shall be resubmitted as soon as corrections can be made.

185.121(3) *Payment.* Within 60 days of the date of receipt of a valid invoice, the department shall make payment in full of all invoices concerning rehabilitative treatment and supportive services rendered to clients, provided the invoices shall be subject to audit and adjustment by the department.

441—185.122(234) Recoupment procedures. Public agencies that are reimbursed more than their actual costs are required to refund any excess to the department within four months of the end of their fiscal year. No provision for profit or other increment above cost is intended in OMB Circular A–87 for public agencies. Those public providers subject to this provision who fail to comply with this requirement shall be considered to be in violation of 185.12(1)"*r*" and subject to sanctions. Providers who do not refund any excess payments within six months of the end of their fiscal year shall be given notice in accordance with 185.12(6) and have any and all payments suspended or withheld in accordance with 185.12(7).

These rules are intended to implement Iowa Code sections 234.6 and 234.38.

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CHAPTERS 186 to 199
Reserved

*Rule 185.4(234), subrule 185.8(4) and rule 185.9(234), effective 8/12/93.
**Effective date of 185.22(1)"*d*,"(2)"*d*," and (3)"*d*," 185.42(3), 185.62(1)"*d*,"(2)"*d*," and (3)"*d*," and 441—185.82(234) delayed 70 days by the Administrative Rules Review Committee at its meeting held July 11, 1995.

1.7(2) For the purpose of this rule, "books, records and documents" shall be defined as any book, record or document pertaining to or prepared or generated by the licensee including, but not limited to, all forms, reports, accounting records, ledgers, subsidiary records, computer-generated data, internal audit records, correspondence, contracts, and personnel records.

1.7(3) All original books, records and documents may be copied and stored on microfilm, microfiche or other suitable media system approved by the administrator.

1.7(4) No original book, record or document, or suitable media copy, may be destroyed by a licensee, for three years, without the prior approval of the administrator.

***491—1.8(17A,99D,99F) Waivers or variances from rules.** This rule outlines a uniform process for the granting of waivers or variances from rules adopted by the commission.

1.8(1) *Commission authority.* A waiver or variance from rules adopted by the commission may be granted in accordance with this rule if: (1) the commission has exclusive rule-making authority to promulgate the rule from which waiver or variance is requested or has final decision-making authority over a contested case in which a waiver or variance is requested; and (2) no statute or rule otherwise controls the grant of a waiver or variance from the rule from which waiver or variance is requested.

1.8(2) *Interpretive rules.* This uniform waiver and variance rule shall not apply to rules that merely define the meaning of a statute or other provisions of law or precedent if the commission does not possess delegated authority to bind the courts to any extent with its definition.

1.8(3) *Compliance with statute.* No waiver or variance may be granted from a requirement that is imposed by statute. Any waiver or variance must be consistent with statute.

1.8(4) *Criteria for waiver or variance.* The commission may issue an order, in response to a completed petition or on its own motion, granting a waiver or variance from a rule adopted by the commission, in whole or in part, as applied to the circumstances of a specified person if the commission finds that:

1. Application of the rule to the person at issue would result in hardship or injustice to that person; and
2. Waiver or variance on the basis of the particular circumstances relative to that specified person would be consistent with the public interest; and
3. Waiver or variance in the specific case would not prejudice the substantial legal rights of any person.

In determining whether waiver or variance would be consistent with the public interest under "2," the commission shall consider whether, if the waiver or variance is granted, the public health and safety will be protected by other means that are substantially equivalent to full compliance with the rule.

a. Commission discretion. The decision on whether the circumstances justify the granting of a waiver or variance shall be made at the discretion of the commission, upon consideration of all relevant factors.

b. Mandatory waivers or variances. In response to the timely filing of a completed petition requesting a waiver or variance, the commission shall grant a waiver or variance from a rule, in whole or in part, as applied to the particular circumstances of a specified person, if the commission finds that the application of all or a portion thereof to the circumstances of that specified person would not, to any extent, advance or serve any of the purposes of the rule.

c. Burden of persuasion. The petitioner shall assume the burden of persuasion when a petition is filed for a waiver or variance from a commission rule.

d. Special waiver or variance rules not precluded. This uniform waiver and variance rule shall not preclude the commission from granting waivers or variances in other contexts or on the basis of other standards if a statute or other commission rule authorizes the commission to do so, and the board deems it appropriate to do so.

e. Administrative deadlines. When the rule from which a waiver or variance is sought establishes administrative deadlines, the commission shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all licensees.

*Effective date of March 15, 2000, delayed 70 days by the Administrative Rules Review Committee at its meeting held March 10, 2000.

1.8(5) *Filing of petition.* A petition for a waiver or variance must be submitted in writing to the commission as follows:

a. License application. If the petition relates to a license application, the petition shall be made in accordance with the filing requirements for the license in question.

b. Contested cases. If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding.

c. Other. If the petition does not relate to a license application or a pending contested case, the petition may be submitted to the commission's administrator.

1.8(6) *Content of petition.* A petition for waiver or variance shall include the following information where applicable and known to the requester:

a. The name, address, and telephone number of the person or entity for whom a waiver or variance is being requested, and the case number of any related contested case.

b. A description and citation of the specific rule from which a waiver or variance is requested.

c. The specific waiver or variance requested, including the precise scope and operative period that the waiver or variance will extend.

d. The relevant facts that the petitioner believes would justify a waiver or variance. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition, and a statement of reasons that the petitioner believes will justify a waiver or variance.

e. A history of any prior contacts between the commission and the petitioner relating to the regulated activity or license affected by the proposed waiver or variance, including a description of each affected license held by the requester, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity or license within the last five years.

f. Any information known to the requester regarding the commission's treatment of similar cases.

g. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question, or which might be affected by the grant of a waiver or variance.

h. The name, address, and telephone number of any person or entity that would be adversely affected by the grant of a petition.

i. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver or variance.

j. Signed releases of information authorizing persons with knowledge regarding the request to furnish the board with information relevant to the waiver or variance.

1.8(7) *Additional information.* Prior to issuing an order granting or denying a waiver or variance, the commission may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the commission may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the commission's administrator, a committee of the commission, or a quorum of the commission.

1.8(8) *Notice.* The commission shall acknowledge a petition upon receipt. The commission shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law, within 30 days of the receipt of the petition. In addition, the commission may give notice to other persons. To accomplish this notice provision, the commission may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law, and provide a written statement to the commission attesting that notice has been provided.

1.8(9) *Hearing procedures.* The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver or variance of rule filed within a contested case, and shall otherwise apply to commission proceedings for a waiver or variance only when the commission so provides by rule or order or is required to do so by statute.

1.8(10) *Ruling.* An order granting or denying a waiver or variance shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

a. Conditions. The commission may condition the grant of the waiver or variance on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

b. Time for ruling. The commission shall grant or deny a petition for a waiver or variance as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the commission shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

c. When deemed denied. Failure of the commission to grant or deny a petition within the required time period shall be deemed a denial of that petition by the commission.

d. Service of order. Within seven days of its issuance, any order issued under this uniform rule shall be transmitted to the petitioner or the person to whom the order pertains, and to any other person entitled to such notice by any provision of law.

1.8(11) *Public availability.* Subject to the provisions of Iowa Code section 17A.3(1)*"e,"* the commission shall maintain a record of all orders granting and denying waivers and variances under this uniform rule. All final rulings in response to requests for waivers or variances shall be indexed and available to members of the public at the commission office.

1.8(12) *Voiding or cancellation.* A waiver or variance is void if the material facts upon which the request is based are not true or if material facts have been withheld. The commission may at any time cancel a waiver or variance upon appropriate notice and hearing if the commission finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver or variance have failed to achieve the objectives of the statute, or the requester has failed to comply with the conditions of the order.

1.8(13) *Violations.* Violation of conditions in the waiver or variance approval is the equivalent of violation of the particular rule for which the waiver or variance is granted and is subject to the same remedies or penalties.

1.8(14) *Defense.* After the commission issues an order granting a waiver or variance, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

1.8(15) *Appeals.* Any request for an appeal from a decision granting or denying a waiver or variance shall be in accordance with the procedures provided in Iowa Code chapter 17A and commission rules. An appeal shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

These rules are intended to implement Iowa Code sections 99D.5 and 99D.6 and chapter 99F.

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TITLE IV
RECREATIONAL VESSEL AND VEHICLE REGISTRATION AND SAFETY

CHAPTER 36
GREEN VALLEY LAKE
SPECIAL WATER ACTIVITY RULES

CHAPTER 37
BOATING SAFETY EQUIPMENT

CHAPTER 38
BOAT REGISTRATION
AND NUMBERING

CHAPTER 39
BOATING PASSENGER CAPACITY

CHAPTER 40
BOATING SPEED AND
DISTANCE ZONING

CHAPTER 34
COMMUNITY FORESTRY GRANT PROGRAM (CFGP)

571—34.1(461A) Purpose. The purpose of this chapter is to define procedures for cost sharing between state and local public agencies or volunteer organizations to assist them in developing comprehensive community street and park tree programs or to establish community tree planting projects on public lands that benefit the citizens of the state of Iowa.

571—34.2(461A) Definitions.

"Administrator" means the administrator of the forestry division of the department, also known as the state forester.

"CFGP" means the community forestry grant program.

"Community" means an incorporated city, town or village within the state of Iowa.

"Department" means the Iowa department of natural resources.

"Director" means the director of the Iowa department of natural resources.

"Division" means the forestry division of the Iowa department of natural resources.

"Iowa urban and community forestry council" means the group of professionals and volunteer leaders selected by the forestry division administrator to advise the division on urban and community forestry programs, also known as the council.

"Organization" means governmental or nongovernmental agencies, formal groups such as service clubs and other volunteer groups.

"Public lands" means land owned by state, county or local governments.

"Urban and community forestry" means the planning, planting and maintenance of trees in communities or public recreation areas.

571—34.3(461A) Availability of funds. Funds to institute the CFGP program may be derived through federal allocations pursuant to Section 9 of the Cooperative Forestry Assistance Act (16 U.S.C. 2105), from state legislative allocations and other sources.

571—34.4(461A) Eligibility of forestry development projects. Forestry development grants (maximum $5,000) may include, but are not necessarily limited to, the following:

1. Hiring a new full- or part-time city forester.
2. Internships for forestry, horticulture or landscape architect to perform community forestry work.
3. Completing a 100 percent street and park tree inventory.
4. City tree ordinance development or revision.
5. City employee or volunteer community forestry training.
6. Development of community forestry master plans.
7. Community forestry youth and adult education programs.
8. City forestry planting site design development.

571—34.5(461A) Eligibility of community tree planting projects. A cost-share grant (maximum $5,000) is available for a community or organization for landscape and conservation tree planting projects.

571—34.6(461A) Projects not eligible. The following types of projects are not eligible for assistance from the CFGP:

1. Acquisition of land.
2. Replacement of normally allocated local government funds.
3. Any type of development or planting that will not improve public benefits or safety.
4. Projects with a total grant request of less than $500.
5. Any project or project costs incurred prior to notification of the sponsoring agency by the forestry division administrator that a grant has been approved.

571—34.7(461A) Eligible applicants. Eligible projects may be submitted by regional or local units of Iowa state, county or city government, local governmental departments, school districts, volunteer organizations and service clubs involved with local urban and community forestry resources. Eligible projects must occur within the state of Iowa.

571—34.8(461A) Establishing project priorities. The forestry division administrator shall appoint a minimum three-member ranking committee representing a cross section of the Iowa urban and community forestry council for the purpose of reviewing, establishing priorities for cost sharing and ranking applications for approval by the administrator. This committee will review and rank all proposals received on a competitive basis for demonstrated need, cash match, community involvement, new project, cost effectiveness, meeting Tree City USA requirements, storm damage documentation and other issues pertinent to urban forestry in Iowa.

571—34.9(461A) Application procedures. Announcements concerning the application procedures will be issued by the administrator each year. A maximum six-page proposal must be received by the Forestry Division Administrator, Wallace State Office Building, Des Moines, Iowa 50319-0034, no later than 4:30 p.m. on the last working day identified in the announcement. The proposal should briefly describe the eligible applicant and detail project request, total budget, source of match and completion date. For community tree planting projects, an 8" × 11" site map must be included in addition to the proposal.

This proposal must be signed by an authorized official of state, regional or local government under whose jurisdiction the project will occur, indicating that the project funds will be spent in accordance with the proposal and all applicable federal and state laws, rules and regulations. The applicant must sign a statement relinquishing the department or the Iowa urban and community forestry council from any liability associated with this project.

571—34.10(461A) Requirements for funding. In order to qualify for funding, state, regional or local units of government, school districts, volunteer organizations and service clubs must comply with the following requirements:

34.10(1) The project(s) must be on public land within the state of Iowa (for example, streets, boulevards, parks, schools, cemeteries).

34.10(2) A $1 for $1 minimum match of requested funds is required.

34.10(3) In-kind contributions are allowed for the forestry development projects only if specific for the proposed project. Tree planting projects require cash match $1 for $1 only. All in-kind costs for the forestry development projects must be documented. Allowable in-kind costs include, but are not limited to, the following:

a. Volunteer labor (reasonable local rates).
b. Value of locally purchased or donated trees to be planted on public areas.
c. Value of wood mulch and other tree protective devices (reasonable local rates).

34.10(4) Only plant materials, products and services purchased from Iowa firms are eligible for tree planting projects.

571—34.11(461A) Project agreements.

34.11(1) A cooperative agreement approved by the administrator between the department and the local grant recipient describing the work to be accomplished and specifying the amount of the grant and the project completion date will be negotiated as soon as possible after a grant has been approved. Maximum time period for project completion shall be stated in the grant announcement, unless an extension approved by the administrator is authorized.

34.11(2) Cooperative agreements between the department and the local grant recipient may be amended to increase or decrease project scope or to increase or decrease project costs and fund assistance. Any increase in fund assistance will be subject to the availability of funds. Amendments to increase scope or fund assistance must be approved by the administrator before work is commenced or additional costs are incurred.

571—34.12(461A) Reimbursement procedures. Financial assistance from the community forestry grant program will be in the form of reimbursement grants which will be made on the basis of the approved percentage of all eligible expenditures up to the amount of the approved grant.

Reimbursement requests must be submitted by the grant recipient on project billing forms provided by the department at the completion of the project.

For forestry development projects and community tree planting projects, grant recipients shall provide documentation as required by the department to substantiate all project expenditures.

Tree planting grant recipient organizations must be willing to sign a ten-year maintenance agreement for trees planted on public lands before reimbursement of costs is approved.

These rules are intended to implement Iowa Code section 461A.2.

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CHAPTER 35
Reserved

CHAPTER 40
STANDARDS FOR PROTECTION AGAINST RADIATION

CHAPTER 38
GENERAL PROVISIONS FOR RADIATION MACHINES AND RADIOACTIVE MATERIALS

641—38.1(136C) Purpose and scope.

38.1(1) Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, by-product material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of May 10, 2000.

38.1(3) The provisions of Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

641—38.2(136C) Definitions. As used in these rules, these terms have the definitions set forth below and are adopted by reference and included herein for 641—Chapters 39 to 45.

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A_2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix E of 641—Chapter 39, Table I, or may be derived in accordance with the procedure prescribed in Appendix E of 641—Chapter 39.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. It is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The units of absorbed dose are the gray (Gy) and the rad.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"Act" means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materials. (Iowa Code chapter 136C)

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

"Adult" means an individual 18 years of age or older.

"Agency" means the Iowa department of public health.

"Agreement state" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particles, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Annually" means at least once every 365 days.

"As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Barrier" (see "Protective barrier").

"Beam axis" means the axis of rotation of the beam-limiting device.

"Beam-limiting device" means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X-ray field or useful beam.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

"Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

"Bone densitometry unit" means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"By-product material" means (1) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "by-product material" within this definition.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method of determining calendar quarters for purposes of these rules except at the beginning of a year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations.

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma w_T H_{T,50}$).

"Constraint" or *"dose constraint"* means a value above which specified licensee actions are required.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 transformations per second (tps).

"Decay-in-storage" means the holding of radioactive material having half-lives of less than 65 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.

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or
2. Release of the property under restricted conditions and termination of the license.

"Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"Detector" (see "Radiation detector").

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

"Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

"Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as 'exposure' or (X), the term "exposure" has a more general meaning in these rules.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Facility" means the location, building, vehicle, or complex under one administrative control, at which radioactive material is stored or used or at which one or more radiation machines are installed, located or used.

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. (1 Gy=100 rad).

"Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual's receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent by the use of individual monitoring devices or by the use of survey data; or
2. Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. See the definition of DAC-hours in 641—Chapter 40.

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescent (OSL) devices, and personal air sampling devices.

"Industrial radiography" means a nondestructive testing method using ionizing radiation, such as gamma rays or X-rays, to make radiographic images.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Instrument traceability" means, for ionizing radiation measurements, the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be from a laboratory accredited by a program which required continuing participation in measurement quality assurance with the National Institute of Standards and Technology or other equivalent national or international program.

"Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Ionizing radiation." See "Radiation."

"Irradiation" means the exposure of a living being or matter to ionizing radiation.

"Kilovolt (kV)(kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. The useful beam, and
2. Radiation produced when the exposure switch or timer is not activated.

"Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

"License" means a license issued by the agency in accordance with the rules adopted by the agency.

"Licensed (or registered) material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license (or registration) issued by the agency.

"Licensed practitioner" means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, dentistry, or certification as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

"Licensee" means any person who is licensed by the agency in accordance with these rules and the Act.

"Licensing state" means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Limits." See "Dose limits."

"Lost or missing licensed (or registered) source of radiation" means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"mA" means milliampere.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 641—subrule 39.5(2).

"Mammogram" means an image produced through radiography of the breast.

"Mammography" means radiography of the breast.

"Mammography unit" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

"Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

"Member of the public" means any individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Misadministration" means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

Involving the wrong patient or human research subject, or wrong radiopharmaceutical; or

When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

3. A gamma stereotactic radiosurgery radiation dose:

Involving the wrong patient or human research subject, or wrong treatment site; or

When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

4. Radiation doses received from teletherapy, linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving the wrong patient or human research subject, wrong mode of treatment or wrong treatment site;

When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. A brachytherapy radiation dose:

Involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

Involving a sealed source that is leaking;

When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration; or when the administered dosage differs from the prescribed dosage; and

When the dose to the patient or human research subject exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include by-product, source, or special nuclear material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

"Nuclear Regulatory Commission (NRC)" means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator." See "Accelerator."

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

"Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

"Personnel monitoring equipment." See "Individual monitoring devices."

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, particle accelerators and X-ray systems, the total dose and dose per fraction as documented in the written directive; or
3. For brachytherapy, either the total source strength and exposure time or the total doses, as documented in the written directive.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

"Primary protective barrier" (see "Protective barrier").

"Principal activities," as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Protective barrier" means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. *"Primary protective barrier"* means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
2. *"Secondary protective barrier"* means a barrier sufficient to attenuate the stray radiation to the required degree.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation possessed by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27) or from voluntary participation in medical research programs.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C) or solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

"Quality factor" (Q) means the modifying factor, listed in Tables I and II of 38.4(4), that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation dose." See "Dose."

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay." See "Bioassay."

"Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

"Recordable event" means the administration of:

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;
2. A radiopharmaceutical or radiation dose where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

a. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

b. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;
5. A teletherapy, particle accelerator or X-ray radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or
6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

"Registrant" means any person who is registered with the agency or is legally obligated to register with the agency pursuant to these rules and the Act.

"Registration" means registration with the agency in accordance with the rules adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure" and 38.4(4)).

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" (see "Protective barrier").

"Shallow dose equivalent" (H,), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means the abbreviation for the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Simulator (radiation therapy simulation system)" means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source" means the focal spot of the X-ray tube.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
2. Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of by-product material as defined by definition (2) of by-product material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology or by a laboratory which participates in continuing measurement quality assurance programs with the National Institute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the agency declares by order to be special nuclear material after the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

"SSD" means the distance between the source and the skin entrance plane of the patient (see "Target-to-skin distance (TSD)").

"Stray radiation" means the sum of leakage and scattered radiation.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Target-to-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron scattering foil to the surface of the irradiated object or patient.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Test" means the process of verifying compliance with an applicable regulation.

"These rules" means 641—Chapters 38 to 45.

"Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 641—40.86(1)*"f."*

"Traceable to a national standard." See "Instrument traceability" or "Source traceability."

"Tube" means an X-ray tube unless otherwise specified. See "X-ray tube."

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual's receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.

"Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (1) not classified as high-level radioactive waste, spent nuclear fuel, or by-product material as defined in Section 11e(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (2) classified as low-level radioactive waste consistent with existing law and in accordance with (1) by the U.S. Nuclear Regulatory Commission.

"Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

"Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are—for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" (WLM) means an exposure to 1 working level for 170 hours—2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user or individual qualified by training and experience to conduct particle accelerator or X-ray therapy prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph "6" of this definition, containing 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: target coordinates, collimator size, plug pattern, and total dose;

4. For teletherapy, particle accelerator or X-ray: the total dose, dose per fraction, treatment site, and overall treatment period;

5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

6. For all other brachytherapy:

a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

"X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

641—38.3(136C) Exemptions from the regulatory requirements.

38.3(1) *General provision.* The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in 641—Chapters 38 to 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Application for exemptions or exceptions should be made in accordance with 641—Chapter 178.

38.3(2) *U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors.* Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under contract receives, possesses, uses, transfers or acquires sources of radiation:

a. Prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

b. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

c. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(1) That the exemption of the prime contractor or subcontractor is authorized by law; and

(2) That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

641—38.4(136C) General regulatory requirements.

38.4(1) *Records.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

38.4(2) *Inspections.*

a. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

38.4(3) *Tests.* Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

a. Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

38.4(4) *Units of exposure and dose.*

a. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

b. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 38.4(4)"*c,*" 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5E–8	2	980E+6	980E+8
	1E–7	2	980E+6	980E+8
	1E–6	2	810E+6	810E+8
	1E–5	2	810E+6	810E+8
	1E–4	2	840E+6	840E+8
	1E–3	2	980E+6	980E+8
	1E–2	2.5	1010E+6	1010E+8
	1E–1	7.5	170E+6	170E+8
	5E–1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.
[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

38.4(5) *Units of activity.* Rescinded IAB 4/8/98, effective 7/1/98.

38.4(6) *Additional requirements.* The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

641—38.5(136C) Administrative actions.

38.5(1) *Enforcement requirements.* Upon determination by the agency that Iowa Code chapter 136C or any rule adopted pursuant to that chapter has been or is being violated, the agency may implement the policies and procedures specified in Bureau of Radiological Health Enforcement Program (BRH-EP-1).

38.5(2) *Impounding.* Sources of radiation shall be subject to impoundment pursuant to the Bureau of Radiological Health Enforcement Program (BRH-EP-1).

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.

641—38.7(136C) Communications.

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.

38.7(2) Drafts of proposed regulations released to the department from the federal government which constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination. Therefore, pursuant to Iowa Code section 22.9, the department waives the provision of Iowa Code section 22.2 as it applies to these proposed draft regulations.

641—38.8(136C) Fees.

38.8(1) *Radiation machines.*

a. Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	$51	$1500
2. Osteopathy	$51	$1500
3. Chiropractic	$51	$1500
4. Dentistry	$39	$1000
5. Podiatry	$39	$1000
6. Veterinary Medicine	$25	--
7. (Industrial/Nonmedical Use)	$50	--
8. Food Sterilization	$1000	--
9. Accelerators	$100	--
10. Electron Microscope	$20	--
11. Bone Densitometry	$25	--

Fees for radiation machines not listed in the above schedule shall not be less than $50 per unit/tube.

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

- $850 for the first unit and, if the facility has additional units at the address of the first unit, a fee of $300 for each additional unit; or
- $850 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria.

(2) Mammography interpretation fees of $100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.

(3) Industrial and oncology accelerator registrants shall pay for each inspection a fee of $400 for the first and $100 for each additional unit.

(4) Industrial radiography X-ray units/walk-in cabinet radiography X-ray unit registrants shall pay for each inspection a fee of $250 for the first unit and $75 for each additional unit.

c. Each person who is engaged in the business of installing or offering to furnish radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or service in the state shall apply for registration of such service with the agency prior to furnishing or offering to furnish any such service. Application shall be on a form provided by the department and include an annual nonrefundable fee of $100.

38.8(2) *Radioactive material licensing, inspection and registration fee.*

a. Licensing.

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa are identical to those specified in 10 CFR 170.31 entitled "Schedule of Fees for Materials Licenses and Other Regulatory Services."

(2) All required fees for new radioactive materials licenses, amendments to licenses, or renewal of licenses shall accompany the application for the requested action.

b. Inspections.

(1) After completion of an inspection, an inspection fee shall be assessed to a facility based on the fees for inspection found in 10 CFR 170.32 entitled "Schedule of Fees for Health and Safety, and Safeguards Inspections for Materials Licenses."

(2) All required fees for inspections conducted by the agency shall be paid within 30 days after receipt of the agency notification following the inspection.

c. Registration. Each person having generally licensed radioactive materials shall annually register with the department and pay a nonrefundable annual fee of $150.

38.8(3) *Industrial radiography testing and certification.*

a. A nonrefundable fee of $125 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

b. A fee of $25 shall be submitted in order to replace lost identification cards issued to industrial radiographers by the agency pursuant to 641—subrule 45.11(3).

38.8(4) *Owner-assessed expenses.* In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the actual expenses incurred by the agency.

38.8(5) *Environmental surveillance fee.* A fee may be levied against any licensee for environmental surveillance activities which are necessary to access the radiological impact of activities conducted by the registrant or licensee. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

38.8(6) *Certification fees.* Diagnostic radiographers, radiation therapists, and nuclear medicine technologists (as defined in 641—Chapter 42), other than licensed practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering 641—Chapter 42. Fees are as follows:

a. Annual fee. Each individual must submit a $45 initial fee for the first year and $35 annually.

b. Examination fee.

(1) Each individual making application to take an examination given by the agency as a general diagnostic radiographer, or general radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of $25 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2000, each individual must pay a nonrefundable fee of $80 each time the individual takes the examination.

(2) Each individual making application to take an examination given by the agency as a limited diagnostic radiographer, limited nuclear medicine technologist, or limited radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of $35 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2001, each individual must pay a nonrefundable fee of $85 each time the individual takes the examination.

(3) Each individual making application to take an examination given by the agency as a general nuclear medicine technologist as defined in 641—Chapter 42 must pay a nonrefundable fee of either $80 or $145, depending upon the testing facility chosen, effective January 1, 2000.

c. Recertification fees. Once certification has been terminated for failure to complete continuing education requirements, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must meet the training and testing requirements of 641—Chapter 42, submit proof of continuing education hours and shall submit a late fee of $30 in addition to the annual fee in order to obtain reinstatement of certification.

38.8(7) *Returned check and late fees.* Persons who fail to pay required fees to the agency are subject to the following penalties:

a. $15 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. $25 for each month for failure to pay annual radiation machine registration or diagnostic radiation operator fee starting the first day of the month after the expiration of the facility's registration or operator's permit to practice. This fee is added to the unpaid annual fee.

38.8(8) *Reciprocity.* Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out-of-state person to operate for a total of 180 days during the 365-day reciprocity period starting the date the fee is received by the agency.

a. Radiation machines. Any out-of-state person who wishes to bring an X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of $100 for each source of radiation pursuant to 38.8(7).

b. Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in 38.8(2) for each 365-day reciprocity period. In addition, if the agency performs an inspection of the out-of-state person's activities while in Iowa, the appropriate inspection fee as specified in 38.8(2) will be assessed.

c. Industrial radiographers wishing to operate in Iowa under an identification card from a jurisdiction recognized by Iowa that charges Iowa card holders a fee will be assessed and must pay a $100 fee prior to conducting industrial radiography in Iowa.

38.8(9) *Radon certification.* Any person wishing to become certified as a radon measurement specialist or radon measurement laboratory is required to pay fees sufficient to defray the cost of administering this chapter. Fees which must be submitted are as follows:

a. Application fee.

(1) Each person with Iowa residency wishing certification under the provisions of 641—43.1(136B) shall pay a nonrefundable $25 application fee.

(2) Each person without Iowa residency wishing certification under 641—43.1(136B) shall pay a nonrefundable $100 application fee.

b. Examination fee. Each person taking the EPA radon proficiency examination shall pay a fee of $125. The fee must be submitted prior to testing.

c. Annual certification fee.

(1) Each individual requesting certification and renewing certification as a radon measurement specialist must pay a nonrefundable annual fee of $250.

(2) Each person requesting certification and renewing certification as a radon measurement laboratory must pay a nonrefundable annual fee of $500.

d. Each person wishing to give reciprocal recognition of credentials from another jurisdiction must pay the appropriate fees as outlined in subrule 38.8(9), paragraphs *"a," "b,"* and *"c."*

e. Returned check and late fees. Persons who fail to pay required fees to the department are subject to the following penalty(ies):

(1) $15 for each insufficient funds check submitted for payment of radon testing or mitigation fees.

(2) $25 per month for failure to pay annual radon testing or mitigation fees starting after the annual renewal month.

38.8(10) *Radon mitigation credentialing.* Any person wishing to become credentialed as a radon mitigation specialist shall be required to pay fees sufficient to defray the cost of administering 641—Chapter 44. Fees which must be submitted are as follows:

a. Application fee.

(1) Each person with Iowa residency wishing certification under the provisions of 641—Chapter 44 shall pay a nonrefundable $25 application fee.

(2) Each person without Iowa residency wishing certification under 641—Chapter 44 shall pay a nonrefundable $100 application fee.

b. Annual credentialing fee.

(1) Each individual requesting credentialing must:

1. Pay an initial fee of $150 which is refundable if credentialing is not completed.

2. Pay annually a renewal fee of $150 or $40 per mitigation system installed (as defined in 641—44.2(136B)) costing more than $200, whichever is larger. With each renewal, a credentialed person must submit legal documentation of the number of mitigation systems installed the previous credentialing year. This number will be used to calculate the renewal fee.

(2) Each person wishing to receive reciprocal recognition of credentialing from another jurisdiction must pay the appropriate fees as outlined in subrule 38.8(9), paragraphs *"a"* and *"b."*

c. Examination fee. Each person taking the EPA Radon Proficiency Examination, if it is administered by the Iowa department of public health, shall pay a fee of $125. The fee must be submitted prior to testing.

38.8(11) *Tanning facility registration/permit fees.* Rescinded IAB 3/25/98, effective 4/29/98.

641—38.9(136C) Procedure for imposing requirements by order, or for modification, suspension, or revocation of a license, registration, or certificate or for imposing civil penalties.

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.

38.9(2) *Notice of violation.*

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) Corrective steps which have been taken by the regulated entity and the results achieved;

(2) Corrective action which will be taken to prevent recurrence; and

(3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

38.9(3) *Orders.*

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;

(2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;

(3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph *"d"* of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) *Settlement and compromise.* At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the chief administrative law judge, may order such adjudication of the issues as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

38.9(5) *Demand for information.*

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity's answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5)*"a"*(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3)*"d."*

38.9(6) *Civil penalties.*

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6)*"b,"* an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6)*"a."*

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6)*"c"* or *"f,"* or the expiration of the time for requesting a hearing described in 38.9(6)*"d,"* the agency may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) *Requests for action under this rule.*

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7)*"b."*

b. Within a reasonable time after a request pursuant to 38.9(7)*"a"* has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c.(1) The bureau chief's decisions under this rule will be filed and within 25 days after the date of the bureau chief's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief's decision under this rule will be entertained by the agency.

641—38.10(136C) Deliberate misconduct.

38.10(1) Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this rule, my not:

a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

b. Deliberately submit to the agency, a licensee, registrant, applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

38.10(2) A person who violates paragraph 38.10(1)*"a"* or *"b"* may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

38.10(3) For the purposes of paragraph 38.10(1)*"a,"* deliberate misconduct by a person means an intentional act or omission that the person knows:

a. Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the agency; or

b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

These rules are intended to implement Iowa Code chapter 136C.

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◊Two ARCs

CHAPTER 39
REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641—39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of May 10, 2000.

39.1(4) In addition to the requirements of this chapter, all registrants are subject to the requirements of 641—Chapters 38 and 40. Furthermore, registrants engaged in healing arts are subject to the requirements of 641—Chapters 41 and 42; registrants engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45.

641—39.2(136C) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 38 may also apply to this chapter.

641—39.3(136C) Requirements for registration of X-ray and other electronic machines that produce radiation.

39.3(1) *Exemptions.*

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 μSv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) *Application for registration of radiation machine facilities.* Each person having a radiation machine facility shall:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a permanent office located in Iowa that has a non-wireless telephone, employee and equipment, and storage for records regarding the equipment and operator certification. Application for registration shall be completed on forms furnished by the agency and shall include the appropriate fee from 641—38.8(136C).

b. Designate on the application form an individual to be responsible for radiation protection.

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3)*"d"* to the registrant's radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).

39.3(3) *Application for registration of servicing and services.*

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of such services with the agency prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions and include the fee required in 641—paragraph 38.8(1)*"c."*

c. Each person applying for registration under this chapter shall specify:

(1) That the person has read and understands the requirements of these rules;

(2) The services for which the person is applying for registration;

(3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;

(4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

d. For the purpose of 39.3(3), services may include but shall not be limited to:

(1) Installation and servicing of radiation machines and associated radiation machine components;

(2) Calibration of radiation machines or radiation measurement instruments or devices;

(3) Radiation protection or health physics consultations or surveys; and

(4) Processor or processor servicing, or both.

e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

39.3(4) *Issuance of notice of registration.*

a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.

b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

39.3(5) *Expiration of notice of registration.* Except as provided by 39.3(6)*"b,"* each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) *Renewal of notice of registration.*

a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).

b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.

39.3(7) *Report of changes.* The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate.

39.3(8) *Approval not implied.* No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall state or imply that any activity under such registration has been approved by the agency.

39.3(9) *Assembler and transfer obligation.*

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency in writing within 15 days of:

(1) The name and address of persons who have received these machines;

(2) The manufacturer, model, and serial number of each radiation machine transferred; and

(3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) *Reciprocity—out-of-state radiation machines.*

a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least three working days before such machine is to be used in the state. The notice shall include:

(1) The type of radiation machine;

(2) The nature, duration, and scope of use;

(3) The exact location(s) where the radiation machine is to be used; and

(4) States in which this machine is registered.

b. If, for a specific case, the two-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

c. The person referred to in 39.3(10)"*a*" shall:

(1) Comply with all applicable rules of the agency;

(2) Supply the agency with such other information as the agency may reasonably request; and

(3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365-day reciprocity period. The 365-day reciprocity period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant's responsibility to ensure the 180-day limit is not exceeded during the 365-day reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365-day reciprocity period.

39.3(11) *Exemption.* Rescinded IAB 4/8/98, effective 7/1/98.

641—39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) *In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41.* Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.

39.4(2) *Source material.*

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

1. Incandescent gas mantles,
2. Vacuum tubes,
3. Welding rods,
4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,

2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22)*"i"*(1).

4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in 39.4(22)*"i"*(1)"8" as required by 641—subrule 40.70(1).

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22)*"i"*(1):

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29)*"h"* or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under 39.4(22)*"i"* or its equivalent, and

2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22)*"i"*(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 39.4(22)*"i"*(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in 39.4(22)*"i"*(1)"8" shall comply with the provisions of 641—subrule 40.70(1) and rules 40.95(136C) and 40.96(136C).

j. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 39.4(22)*"j"*(1):

1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.70(1);

2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrule 40.70(1), and rules 40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

39.4(23) Reserved.

39.4(24) *Filing application for specific licenses.*

a. Applications for specific licenses shall be filed on a form prescribed by the agency and include the fee required in 641—subrule 38.8(2).

b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

f. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)"*f*"(1)"1" of this subrule:

1. The radioactive material is physically separated so that only a portion could be involved in an accident;

2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix G due to the chemical or physical form of the material;

4. The solubility of the radioactive material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix G;

6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix G; or

7. Other factors appropriated for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)"*f*"(1)"2" must include the following information:

1. Facility description. A brief description of the licensee's facility and area near the site.

2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

8. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

9. Information to be communicated. A brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub.L.No. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

39.4(25) *General requirements for the issuance of specific licenses.* A license application will be approved if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public; and

d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), or 641—Chapter 45.

e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

39.4(26) *Financial assurance and record keeping for decommissioning.*

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding $1.0E^5$ times the applicable quantities set forth in Appendix F of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26)*"e."* The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

b. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 39.4(26)*"d"* shall either:

(1) Submit a decommissioning funding plan as described in 39.4(26)*"e"*; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26)*"d"* using one of the methods described in 39.4(26)*"f."* For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f"* is submitted to the agency.

c. (1) Each holder of a specific license issued on or after July 1, 1993, which is of a type described in 39.4(26)*"a"* or *"b,"* shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.

(2) Each holder of a specific license issued before July 1, 1993, and of a type described in 39.4(26)*"a,"* shall submit, on or before July 1, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36)*"b,"* shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^4 is greater than 1, but R divided by 10^5 is less than or equal to 1.)	750,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix F of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^3 is greater than 1, but R divided by 10^4 is less than or equal to 1.)	150,000

Greater than 10^{10} times the applicable quantities of Appendix F or 641—Chapter 40 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 39.4(26)*"a,"* divided by 10^{10} is greater than 1.) 75,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 39.4(26)*"f,"* including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate and a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f."*

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix H of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I of this chapter. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J of this chapter. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of paragraph 39.4(26)*"f"* or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

1. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in effect until the agency has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26)*"f"*(2).

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 39.4(26)*"d,"* and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. All areas designated as restricted areas as defined under 641—38.2(136C);
2. All areas outside of restricted areas that require documentation under 641—39.4(26)*"g"*(1);
3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 641—40.88(136C); and
4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 641—40.71(136C).

39.4(27) *Special requirements for issuance of certain specific licenses for radioactive material.*

a. to *d.* Reserved.

e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if the application contains:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,

2. Periodic training,
3. On-the-job training, and
4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;

(2) Written operating and emergency procedures, including all items listed in Appendix D of 641—Chapter 45;

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any of the following applies to the location:

1. Non-wireless telephone service is established by the licensee;
2. Industrial radiographic services are advertised for or from the location;
3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;

(5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;

(6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 641—subrule 45.1(8) and 641—Chapter 45, Appendix A); and

(7) If a license application includes underwater radiography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and
3. Methods for gas-tight encapsulation of equipment;

(8) If a license application includes offshore platform or lay-barge radiography, a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;
2. Storage facilities for radioactive material; and
3. Methods for restricting access to radiation areas.

39.4(28) *Special requirements for specific licenses of broad scope.* This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

a. The different types of broad scope licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

h. Except as provided in 39.4(33)*"i,"* licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

i. The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(1) It is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) A significant volume reduction exposure to workers can be achieved by allowing short-lived radionuclides to decay;

(4) A significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than a deferred cleanup, and other factors beyond the controls of the licensee.

j. As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed IDPH Form 588-2793 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

1. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report the level of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per liter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

2. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the agency determines that:

(1) By-product material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) A radiation survey has been performed which demonstrates that the premises are suitable for release or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C).

(4) Records required by 39.4(52)*"e"* and 39.4(52)*"g"* have been received.

l. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

m. If licensed activities are transferred or assigned in accordance with 39.4(32)*"b,"* each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

n. Prior to license termination, each licensee shall forward the records required by 39.4(26)*"g"* to the agency.

39.4(34) *Renewal of licenses.*

a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24) and include the fees required in 641—subrule 38.8(2).

b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

39.4(35) *Amendment of licenses at request of licensee.* Applications for amendment of a license shall be filed in accordance with 39.4(24), include the fees required in 641—subrule 38.8(2), and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

39.4(36) *Agency action on applications to renew or amend.* In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.

39.4(37) *Persons possessing a license for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these rules.* Any person who, on the effective date of these rules, possesses a general or specific license issued by the U.S. Nuclear Regulatory Commission for source, by-product, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a like license issued under this chapter and the Iowa Code, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

39.4(38) *Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these rules.* Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) and **39.4(40)** Reserved.

39.4(41) *Transfer of material.*

a. No licensee shall transfer radioactive material except as authorized pursuant to 39.4(41).

b. Except as otherwise provided in the license and subject to the provisions of 39.4(41)*"c"* and *"d,"* any licensee may transfer radioactive material:

(1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or

(5) As otherwise authorized by the agency in writing.

c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by 39.4(41)*"c"* is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 39.4(41)*"d"*(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to **39.4(50)** Reserved.

39.4(51) *Modification and revocation of licenses.*

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Iowa Code, or of the license, or of any rule, regulation, or order of the agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

39.4(52) *Records.*

a. Each person who receives by-product material pursuant to a license shall keep records showing the receipt, transfer, and disposal of the by-product material as follows:

(1) The licensee shall retain each record of receipt of by-product material as long as the material is possessed and for three years following transfer or disposal of material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these rules dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of by-product material until the agency terminates each license that authorizes disposal of the material.

b. The licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition; the record must be retained until the agency terminates each license that authorizes the activity that is subject to the record-keeping requirements.

c. Records which must be maintained may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. If there is a conflict between the agency's rules or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in these rules for such records shall apply unless the agency has granted a specific exemption from the record retention requirements specified in agency rules.

e. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Records of disposal of licensed material made under 641—40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

f. If licensed activities are transferred or assigned, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

g. Prior to license termination, each licensee shall forward the records required by subrule 39.4(26) to the agency.

39.4(53) to **39.4(89)** Reserved.

39.4(90) *Reciprocal recognition of licenses.*

a. Licenses of by-product, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90)*"a"*(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three working days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)*"a."*

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)*"a"* except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3)*"a."*

(7) Notwithstanding the provisions of 39.4(90)"*a*"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)"*d*"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;
3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)"*d*" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)"*h.*"

b. Licenses of naturally occurring or accelerator-produced radioactive material.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90)"*a*"(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)"*b.*"

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other information as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)"*b*" except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3)"*a.*"

(7) Notwithstanding the provisions of 39.4(90)"*b*"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)"*d*"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)"*d*" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)*"h."*

39.4(91) to **39.4(104)** Reserved.

641—39.5(136C) Transportation of radioactive material. All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the provision contained in 10 CFR Part 71 as it applies to the state of Iowa.

CHAPTER 39—APPENDIX A
EXEMPT CONCENTRATIONS

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	

Element (atomic number)	Radionuclide	Column I Gas concentration μCi/ml 1/	Column II Liquid and solid concentration μCi/ml 2/
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

1/ Values are given in Column I only for those materials normally used as gases.

2/ μCi/g for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of 39.4(3) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

EXAMPLE: $\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} < 1$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} MBq/l)

CHAPTER 39—APPENDIX B
EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100

Radioactive Material	Microcuries
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100

Radioactive Material	Microcuries
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10

Radioactive Material	Microcuries
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10

Radioactive Material	Microcuries
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

NOTE 1: For purposes of 39.4(25)"*f*"(5)"2" where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Radionuclide A possessed}}{1000 \times \text{Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{1000 \times \text{Appendix B quantity for Radionuclide B}} \mu 1$$

NOTE 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

CHAPTER 39—APPENDIX C
Reserved

CHAPTER 39—APPENDIX D
LIMITS FOR BROAD LICENSES (39.4(28))

Radioactive Material	Column I curies	Column II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1

Radioactive Material	Column I curies	Column II curies
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.

Radioactive Material	Column I curies	Column II curies
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1

Radioactive Material	Column I curies	Column II curies
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001

Radioactive Material	Column I curies	Column II curies
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1

Radioactive Material	Column I curies	Column II curies
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1

Radioactive Material	Column I curies	Column II curies
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

CHAPTER 39—APPENDIX E
DETERMINATION OF A_1 AND A_2

Rescinded IAB 4/5/00, effective 5/10/00

CHAPTER 39—APPENDIX F
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction.

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test.

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; a ratio of current assets to current liabilities greater than 1.5; and

(2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least $10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, or Baa as issued by Moody's; and

(2) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(3) Tangible net worth of at least $10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform BRH within 90 days or any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the BRH of intent to establish alternate financial assurance as specified in BRH rules. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee.

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the BRH. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and BRH, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in BRH rules within 90 days after receipt by the licensee and BRH notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the BRH has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to BRH. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

CHAPTER 39—APPENDIX G
QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-173	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000

Radioactive Material	Release Fraction	Quantity (curies)
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-58	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000

Radioactive Material	Release Fraction	Quantity (curies)
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[2]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[2]	.0001	20
Combinations of radioactive materials listed above[1]	------	------

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Appendix G exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

CHAPTER 39—APPENDIX H
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

2. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the agency of its intent to establish alternate financial assurance as specified in these rules within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX I
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet the following criteria:

1. Tangible net worth greater than $10 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send notice to the agency of intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 39—APPENDIX J
CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities to pass the financial test, a college or university must meet either the criteria in Section II.A.1. or the criteria in Section II.A.2. of this appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals to pass the financial test, a hospital must meet either the criteria in Section II.B.1. or the criteria in Section II.B.2. of this appendix:

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long-term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform this agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to this agency of its intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service.

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 40
STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These rules are issued pursuant to the authority in Iowa Code section 136C.3 and 136C.4.

40.1(2) The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

40.1(3) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public interest.

40.1(4) Except as specifically provided in other parts of these rules, this chapter applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before May 10, 2000.

40.1(6) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 45.

641—40.2(136C) Definitions.

40.2(1) For the purposes of this chapter, the definitions of 641—Chapter 38 may also apply.

40.2(2) As used in this chapter, these terms have the definitions set forth below.

"Annual limit on intake (ALI)" means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

"Derived air concentration (DAC)" means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration-hour (DAC-hour)" means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed dose equivalent of 5 rem (0.05 Sv).

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Inhalation class" (see "Class.")

"Lung class" (see "Class.")

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference person" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.

"Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.
[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

641—40.3(136C) Implementation.

40.3(1) Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

40.3(2) If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

40.3(3) If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

641—40.4 to **40.9** Reserved.

RADIATION PROTECTION PROGRAMS

641—40.10(136C) Radiation protection programs.

40.10(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See 40.81(136C) for record-keeping requirements relating to these programs.

40.10(2) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

40.10(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

40.10(4) To implement the ALARA requirements of 40.10(2), and notwithstanding the requirements in 641—40.26(136C), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 641—40.97(136C) and promptly take appropriate corrective action to ensure against recurrence.

641—40.11 to **40.14** Reserved.

OCCUPATIONAL DOSE LIMITS

641—40.15(136C) Occupational dose limits for adults.

40.15(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 40.20(136C), to the following dose limits:

a. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

b. The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(1) A lens dose equivalent of 15 rem (0.15 Sv), and

(2) A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

40.15(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 40.20(5)*"a"* and *"b."*

40.15(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

40.15(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 40.86(136C).

40.15(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

40.15(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 40.19(5).

641—40.16(136C) Compliance with requirements for summation of external and internal doses.

40.16(1) If the licensee or registrant is required to monitor pursuant to both 40.19(1) and 40.19(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), or only pursuant to 40.19(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 40.16(2), 40.16(3) and 40.16(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

40.16(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

a. The sum of the fractions of the inhalation ALI for each radionuclide, or

b. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

b. Accept, as the record of lifetime cumulative radiation dose, an up-to-date IDPH Form 588-2833 or equivalent signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

c. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

40.19(4) *a.* The licensee or registrant shall record the exposure history, as required by 40.37(136C), on IDPH Form 588-2833 or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing IDPH Form 588-2833 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on IDPH Form 588-2833 or equivalent indicating the periods of time for which data are not available.

b. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on IDPH Form 588-2833 or equivalent on or before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

40.19(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

a. In establishing administrative controls pursuant to 40.15(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

b. That the individual is not available for planned special exposures.

40.19(6) The licensee or registrant shall retain the records on IDPH Form 588-2833 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing IDPH Form 588-2833 or equivalent for three years after the record is made.

641—40.20(136C) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 40.15(136C) provided that each of the following conditions is satisfied:

40.20(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

40.20(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

40.20(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

a. Informed of the purpose of the planned operation; and

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

40.20(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 40.19(2) during the lifetime of the individual for each individual involved.

40.20(5) Subject to 40.15(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

a. The numerical values of any of the dose limits in 40.15(1) in any year; and

b. Five times the annual dose limits in 40.15(1) during the individual's lifetime.

40.20(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 40.85(136C) and submits a written report in accordance with 40.98(136C).

40.20(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 40.15(1) but shall be included in evaluations required by 40.20(1) and 40.20(2).

641—40.21(136C) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 40.15(136C).

641—40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 40.86(136C) for record-keeping requirements.

40.22(2) The licensee or registrant shall make efforts to avoid substantial variation[1] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 40.22(1).

40.22(3) The dose equivalent to an embryo/fetus shall be taken as the sum of:

a. The deep dose equivalent to the declared pregnant woman; and

b. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

641—40.23 to **40.25** Reserved.

[1] The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

40.32(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

40.32(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the Agency.

40.32(5) The following shall be considered evidence that a sealed source is leaking:

a. The presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample.

b. Leakage of 0.001 μCi (37 Bq) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

c. The presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

40.32(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this chapter.

40.32(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 40.102(136C).

641—40.33 to **40.35** Reserved.

SURVEYS AND MONITORING

641—40.36(136C) Surveys and monitoring—general.

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys that:

a. Are necessary for the licensee or registrant to comply with this chapter; and

b. Are necessary under the circumstances to evaluate:

(1) The magnitude and extent of radiation levels; and

(2) Concentrations or quantities of radioactive material; and

(3) The potential radiological hazards that could be present.

40.36(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable part of these rules or a license condition.

40.36(3) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 40.15(136C), with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

a. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

b. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

40.36(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

641—40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

40.37(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

a. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 40.15(1); and

b. Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in 40.21(136C) or 40.22(136C); and

c. Individuals entering a high or very high radiation area.

d. Individuals working with medical fluoroscopic equipment.

40.37(2) Each licensee or registrant shall monitor, to determine compliance with 40.18(136C), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

a. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

b. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 40.37(136C) wear individual monitoring devices 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 is typically at the neck (collar);

b. 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. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 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. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 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.

641—40.38 to **40.41** Reserved.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

641—40.42(136C) Control of access to high radiation areas.

40.42(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

a. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

40.61(4) *Posting of airborne radioactivity areas.* The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

40.61(5) *Posting of areas or rooms in which licensed or registered material is used or stored.* The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

641—40.62(136C) Exceptions to posting requirements.

40.62(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

a. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

b. The area or room is subject to the licensee's or registrant's control.

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 40.61(136C) provided that the patient could be released from licensee control pursuant to 641—subrule 41.2(27).

40.62(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

40.62(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 641—40.61(136C) if:

a. Access to the room is controlled pursuant to 641—subrule 41.2(53); and

b. Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

641—40.63(136C) Labeling containers and radiation machines.

40.63(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

40.63(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

40.63(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

641—40.64(136C) Exemptions to labeling requirements. A licensee is not required to label:

40.64(1) Containers holding licensed materials in quantities less than the quantities listed in Appendix C; or

40.64(2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

40.64(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter; or

40.64(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation;[2] or

[2] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

c. If more than one radionuclide is released, the following conditions must also be satisfied:

(1) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(2) The sum of the fractions for each radionuclide required by 40.72(1)*"c"*(1) does not exceed unity; and

d. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 Ci (185 GBq) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

40.72(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 40.72(1).

641—40.73(136C) Treatment or disposal by incineration. A licensee may treat or dispose of licensed materials by incineration only in the amounts and forms specified in 40.74(136C) or as specifically approved by the Agency pursuant to 40.71(136C).

641—40.74(136C) Disposal of specific wastes.

40.74(1) A licensee may dispose of the following licensed material as if it were not radioactive:

a. 0.05 μCi(1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

b. 0.05 μCi (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

40.74(2) A licensee shall not dispose of tissue pursuant to 40.74(1)*"b"* in a manner that would permit its use either as food for humans or as animal feed.

40.74(3) The licensee shall maintain records in accordance with 40.88(136C).

641—40.75(136C) Transfer for disposal and manifests.

40.75(1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

40.75(2) Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix D of this chapter.

40.75(3) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D of this chapter.

641—40.76(136C) Compliance with environmental and health protection regulations. Nothing in 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C) relieves the licensee or registrant from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C).

641—40.77 to **40.79** Reserved.

RECORDS

641—40.80(136C) General provisions.

40.80(1) Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

40.80(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

40.80(3) In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in 40.80(1). However, all quantities must be recorded as stated in 40.80(1).

40.80(4) Notwithstanding the requirements of 40.80(1), when recording information on shipment manifests, as required in 641—40.75(136C), information must be recorded in the International System of Units (SI) or in SI and units as specified in 40.80(1).

641—40.81(136C) Records of radiation protection programs.

40.81(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

a. The provisions of the program; and

b. Audits and other reviews of program content and implementation.

40.81(2) The licensee or registrant shall retain the records required by 40.81(1)*"a"* until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 40.81(1)*"b"* for three years after the record is made.

641—40.82(136C) Records of surveys.

40.82(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 40.36(136C) and 40.65(2). The licensee or registrant shall retain these records for three years after the record is made.

40.82(2) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

a. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

b. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

NOTE: For purposes of 40.61(5), 40.64(1), and 40.95(1) where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1"—that is, unity.

CHAPTER 40

APPENDIX D

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND MANIFESTS

As used in this appendix, the following definitions apply:

"Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

"Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.

"Decontamination facility" means a facility operating under an Agreement State or Nuclear Regulatory Commission license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives and, for purposes of this appendix, is not considered to be a consignee for LLW shipments.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"EPA identification number" means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

"Forms 540, 540A, 541, 541A, 542, and 542A" are official forms referenced in this appendix. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Forms 541 (and 541A) and Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Generator" means a licensee operating under an Agreement State or Nuclear Regulatory Commission license who (1) is a waste generator as defined in this rule, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

"High integrity container (HIC)" means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet United States Department of Transportation requirements for a Type A package.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this appendix, a "geologic repository" as defined in 10 CFR Part 60 is not considered a land disposal facility.

"Package" means the assembly of components necessary to ensure compliance with the packaging requirements of United States Department of Transportation regulations, together with its radioactive contents, as presented for transport.

"Physical description" means the items called for on Form 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means Form 540 and, if required, Form 540A which includes the information required by United States Department of Transportation in 49 CFR Part 172.

"Uniform Low-Level Radioactive Waste Manifest" or "uniform manifest" means the combination of Forms 540, 541 and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on Form 541.

"Waste generator" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste processor" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by this agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7232.

This appendix includes information requirements of the United States Department of Transportation, as codified in 49 CFR Part 172. Information on hazardous, medical, or other waste required to meet Environmental Protection Agency regulations, as codified in 40 CFR Parts 259, 261, or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

Information Requirements

A. General Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility's address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number, for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides, H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multigenerator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this appendix.) It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the United States Department of Transportation and this agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1. through A.9. of this appendix. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4. through A.9. of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with 10 CFR 61.55;

3. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

6. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5. of this section;

7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41); and

9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

4. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3. of this section;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph E.1. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR 61.55 and 61.57;

5. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

7. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6. of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and this agency of any shipment, or part of a shipment, that has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the license is terminated; and

3. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with this agency. Each licensee who conducts a trace investigation shall file a written report with this agency within two weeks of completion of the investigation.

CHAPTER 40

APPENDIX E

CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

I. Classification of Radioactive Waste for Land Disposal

a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b) Classes of waste.

1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II. (a). If Class A waste also meets the stability requirements set forth in Section II. (b), it is not necessary to segregate the waste for disposal.

2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE I

Radionuclide	Concentration curie/cubic meter[a]	nanocurie/gram[b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a] To convert the Ci/m^3 values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37.
[b] To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

1) If the concentration does not exceed the value in Column 1, the waste is Class A.

2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE II

Radionuclide	Concentration, curie/cubic meter *		
	Column 1	Column 2	Column 3
Total of all radionuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*AGENCY NOTE: To convert the Ci/m^3 value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m^3 value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

g) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

h) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m^3 (50 Ci/m^3) and Cs-137 in a concentration of 814 GBq/m^3 (22 Ci/m^3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

II. Radioactive Waste Characteristics

a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this chapter, the site license conditions shall govern.

2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4) Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.[4]

8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 100 Ci (3.7 TBq) per container.

[4]See 641—38.2 of these rules for the definition of pyrophoric.

9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

CHAPTER 40

APPENDIX F
QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie*
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1

Material	Microcurie*
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100

Material	Microcurie*
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1

Material	Microcurie*
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)**	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10

Material	Microcurie*
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha-emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

*To convert μCi to kBq, multiply the μCi value by 37.
**Based on alpha disintegration rate of U-238, U-234, and U-235.

NOTE: This Appendix is retained for use by those Agreement States that need to adopt decommissioning regulations compatible with the U.S. Nuclear Regulatory Commission.

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1"—that is, unity.

These rules are intended to implement Iowa Code chapter 136C.

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CHAPTER 41
SAFETY REQUIREMENTS FOR THE USE OF RADIATION MACHINES AND CERTAIN USES OF RADIOACTIVE MATERIALS

641—41.1(136C) X-rays in the healing arts.

41.1(1) *Scope.* This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this rule are in addition to, and not in substitution for, any other applicable provisions of these rules. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of May 10, 2000.

41.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer"). (Includes devices such as phototimers and ion chambers.)

"Base density" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cassette" means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the "Radiation Control for Health and Safety Act of 1968," the Food and Drug Administration.

"Certified system" means any X-ray system which has one or more certified component(s).

"Coefficient of variation" or *"C"* means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\sum_{i=1}^{n} \frac{(x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:
s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

"Control chart" means a chart used to record (and control) the results of quality control testing as a function of time.

"Control limit" means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

"Control panel" (see X-ray control panel).

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (see "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Densitometer" means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

"Detents" means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

"Developer" means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

"Developer replenishment" means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

"Diagnostic mammography" means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (see "X-ray equipment").

"Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fixer" means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

"Fixer retention" means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (actual)" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Fog" means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

"General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)*"a"*(7).

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp × mA × second.

"Image contrast" means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attentuation difference or light exposure difference.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

"Image noise" See "Radiographic noise."

"Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image sharpness" means the overall impression of detail and clarity in a radiographic image.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Kilovolts peak" (see "Peak tube potential").

"kVp" (see "Peak tube potential").

"kWs" means kilowatt second.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = 100 $(V_n-V_l)/V_l$

where

V_n = No-load line potential and

V_l = Load line potential.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

"Mobile X-ray equipment" (see "X-ray equipment").

"PBL" (see "Positive beam limitation").

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see "Automatic exposure control").

"PID" (see "Position indicating device").

"Portable X-ray equipment" (see "X-ray equipment").

"Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Processor" means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

"Protective apron" means an apron made of radiation-absorbing materials used to reduce radiation exposure.

"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

"Quality assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiographic contrast" means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

"Radiographic noise" means unwanted fluctuations in optical density on the screen-film image.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from X-ray photons.

"Repeat (or reject) analysis" means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

"Replenishment rate" means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Safelight" means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

"Screen" means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

"Screen-film combination" means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

"Screen-film contact" means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

"Sensitometer" means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

"Sensitometric strip" means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

"Sensitometry" means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

"SID" (see "Source-image receptor distance").

"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stationary X-ray equipment" (see "X-ray equipment").

"Technique factors" means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

"Viewbox" means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"X-ray control panel" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

"X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

"X-ray exposure control" means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) *Administrative controls.*

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control and for having the following minimum tests performed every two years by a registered service facility:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6).
2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7).
3. Fluoroscopic: entrance exposure rate (641—41.1(5)*"c"*), minimum SSD (641—41.1(5)*"f"*).
4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant's agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's anatomical size versus technique factors to be utilized;
2. Type and size of the film or film-screen combination to be used;
3. Type and focal distance of the grid to be used, if any;
4. Source to image receptor distance to be used, except for dental intra-oral radiography; and
5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and
2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)*"a"*(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)*"a"*(4), shall list individual projections where holding devices cannot be utilized;
2. Written safety procedures, as required by 41.1(3)*"a"*(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
3. The human holder shall be protected as required by 41.1(3)*"a"*(5)"2";
4. No individual shall be used routinely to hold film or patients; and
5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.
2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.
4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.
5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(3) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.
2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.

(12) Fluoroscopic equipment shall be used only under the direct supervision of a licensed practitioner.

b. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) Model and serial numbers of all major components and user's manual for those components;

(2) Tube rating charts and cooling curves;

(3) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(4) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and approval. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer.

2. Processing deviations from the requirements of 41.1(3)*"f"* shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3)*"f"* are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

41.1(4) *General requirements for all diagnostic X-ray systems.* In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μC/kg) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)"*e*" shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)"*e*"(1)"1" is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)*"h"*(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

41.1(5) *Fluoroscopic X-ray systems except for computed tomography X-ray systems.* All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)*"a"*(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;
- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;
- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;
- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;
- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5)*"a"*(2) and 41.1(5)*"a"*(3), that means:

1. Shall be designed for use only in the event of system failure;

2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)*"a," "c," "d,"* and *"g"* provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)*"g"* are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6)*"h"*(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.
- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)*"a"*(1)"1" and "2" provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)*"a"*(1)"1" and "2"; and the purpose of 41.1(6)*"a"*(1)"1" and "2" will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)*"a"*(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X-ray systems other than those described in 41.1(6)*"a"*(1), (2), and (3), and veterinary systems installed prior to July 1, 1998.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)*"a"*(5)"1" and "2" may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)*"a"*(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)*"b"*(2)"2"; or
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly.

Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. Rescinded IAB 4/5/00, effective 5/10/00.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when:

• Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6)*"h"*(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

• The sum of the length and width differences as stated in 41.1(6)*"h"*(2)"1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6)*"h"*(2)"1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6)*"h"*(2)"1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6)*"a"* or 41.1(6)*"h"*(2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

41.1(7) *Intraoral dental radiographic systems.* In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used.

a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)*"c."*

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (½) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)*"a"*(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)*"c"*(5)"1."
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. kVp limitations. Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-held during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7)*"b"*(1).

(4) Dental fluoroscopy without image intensification shall not be used.

41.1(8) Rescinded IAB 6/4/97, effective 7/9/97.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months.

c. Operators, other than physicians, must possess a health education background to include anatomy and physiology and must complete the manufacturer's training session pertaining to bone densitometry or equivalent. A permit to practice for operators is not required.

d. Specific operating procedures must be prepared and made available at the operator's position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) *Veterinary medicine radiographic installations.*

a. Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4)*"c."*

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. Operator protection.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 40.21(136C) and subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures.

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) *Computed tomography X-ray systems.*

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from –7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\text{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

41.2(14) *Records and reports of misadministrations.*

a. When a misadministration involves any therapy procedure, 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. 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 including remedial care as a result of the misadministration 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. 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, a written report to the patient or the human research subject by sending either:

1. A copy of the report that was submitted to the agency; or
2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. When a misadministration involves a diagnostic procedure, the radiation safety officer shall promptly investigate its cause, make a record for agency review, and retain the record as directed in 41.2(14)*"d."* The licensee shall also notify the referring physician and the agency in writing on IDPH Form #588-2608 or equivalent within 15 days if the misadministration involved the use of radioactive material not intended for medical use, administration of dosage five-fold different from the intended dosage, or administration of radioactive material such that the patient or human research subject is likely to receive a dose exceeding 5 rem (0.05 Sv) effective dose equivalent or 50 rem (0.5 Sv) dose equivalent to any individual organ. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

d. Each licensee shall retain a record of each misadministration for ten years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14)*"a"* to 41.2(14)*"d"* shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Written directives. Each licensee shall meet the following objectives:

(1) That, prior to administration, a written directive[1] is prepared for:

1. Any teletherapy radiation dose;
2. Any gamma stereotactic radiosurgery radiation dose;
3. Any brachytherapy radiation dose;
4. Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or
5. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, 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;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(6) The licensee shall retain:

1. Each written directive; and
2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in 41.2(14)*"f"*(1) in an auditable form, for three years after the date of administration.

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[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 will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

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 will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

g. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

41.2(59) *Periodic spot checks.*

a. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

b. To satisfy the requirement of 41.2(59)*"a,"* spot checks shall include determination of:

(1) Timer constancy and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and

(6) The difference between the measurement made in 41.2(59)*"b"*(5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

c. A licensee shall use the dosimetry system described in 41.2(57) to make the spot check required in 41.2(59)*"b"*(5).

d. A licensee shall perform spot checks required by 41.2(59)*"a"* in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

e. A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for three years.

f. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.

g. To satisfy the requirement of 41.2(59)*"f,"* safety spot checks shall ensure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off."

h. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the agency.

i. A licensee shall promptly repair any system identified in 41.2(59)*"g"* that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

j. A licensee shall maintain a record of each spot check required by 41.2(59)*"a"* and *"f"* for three years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

41.2(60) *Radiation surveys for teletherapy facilities.*

a. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 41.2(51), the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 41.2(18) to verify that:

(1) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 μSv) per hour and 2 millirems (20 μSv) per hour, respectively; and

(2) With the teletherapy source in the "on" position with the largest clinically available treatment field, and with a scattering phantom in the primary beam of radiation, that:

1. Radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in 641—40.15(136C); and

2. Radiation dose rates in controlled or unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in 641—40.26(136C).

b. If the results of the surveys required in 41.2(60)*"a"* indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(2) Until the licensee has received a specific exemption from the agency.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59)*"g"* for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)*"a"* indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62)*"a,"* and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Five-year inspection.*

a. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. 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 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) *Radiation safety officer.* Except as provided in 41.2(66), an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) shall:

a. Be certified by the:

(1) American Board of Health Physics in comprehensive health physics;

(2) American Board of Radiology in radiological physics, therapeutic radiological physics, or medical nuclear physics;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine.

b. Have had 200 hours of classroom and laboratory training as follows:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology;

(5) Radiopharmaceutical chemistry; and

(6) One year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

41.2(66) *Training for experienced radiation safety officer.* An individual identified as a radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license on September 1, 1992, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 41.2(65).

41.2(67) *Training for uptake, dilution, or excretion studies.* Except as provided in 41.2(75) and 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(31) to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiation biology; and
5. Radiopharmaceutical chemistry.

(2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
3. Administering dosages to patients or human research subjects and using syringe radiation shields;
4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
5. Patient or human research subject follow-up; or

c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(67)*"b"*;

d. Be identified on a current Agreement State or NRC license as an authorized user for use listed in 41.2(31).

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;
2. Selecting the proper dose and how it is to be administered;
3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and
4. Postadministration follow-up and review of case histories;

c. Be identified on a current Agreement State or NRC license as an authorized user for teletherapy.

41.2(74) *Training for teletherapy physicist.* The licensee shall require the teletherapy physicist to:

a. Be certified by:

(1) The American Board of Radiology in:

1. Therapeutic radiological physics;
2. Roentgen-ray and gamma-ray physics;
3. X-ray and radium physics; or
4. Radiological physics; or
5. The American Board of Medical Physics in radiation oncology physics; or

(2) Reserved; or

b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.2(21), 41.2(58), 41.2(59), and 41.2(60) under the supervision of a teletherapy physicist during the year of work experience.

c. Be identified on a current Agreement State or NRC license as a teletherapy physicist.

41.2(75) *Training for experienced authorized users.* Rescinded IAB 8/3/94, effective 9/7/94.

41.2(76) *Physician training in a three-month program.* A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 41.2(67) or 41.2(68).

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(79) 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 was completed.

41.2(78) *Training for an authorized nuclear pharmacist.* The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties, or

b. Has completed:

(1) 700 hours in a structured educational program consisting of both:

1. Didactic 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. Supervised experience in a nuclear pharmacy involving the following:

- Shipping, receiving, and performing related radiation surveys;
- Using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- Using administrative controls to avoid mistakes in the administration of radioactive material;
- Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

41.2(79) *Training for experienced nuclear pharmacists.* A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 41.2(78)*"b"* before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in 41.2(78)*"b"*(2) and recentness of training in 41.2(77) to qualify as an authorized nuclear pharmacist.

641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

"Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit (MU)." See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, or exit window, of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
2. For X-ray irradiation target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Radiation field." See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 41.3(4)*"d."*

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5)*"b"* above, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4)*"b"* above, training shall be under the supervision of an authorized user and shall include:

(1) Reviewing the full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5)*"b,"* the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Medical Physics; or

e. Hold a master's or doctorate degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16)*"a"*(1), 41.3(17)*"c,"* 41.3(17)*"c"*(5), 41.3(18)*"e,"* and 41.3(18)*"f"* under the supervision of a radiation therapy physicist during the year of work experience.

f. Notwithstanding the provisions of 41.3(6)*"e,"* certification pursuant to 41.3(6)*"b,"* 41.3(6)*"c"* or 41.3(6)*"d"* shall be required on or before December 31, 1999, for all persons currently qualifying as a radiation therapy physicist pursuant to 41.3(6)*"e."*

41.3(7) Qualifications of operators.

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable.

b. Each operator's permit to practice under 641—Chapter 42 shall be posted in the immediate vicinity of the general work area and visible to the public.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user under the following conditions:

a. The authorized user has the prior written permission of the registrant's management if the use occurs on behalf of an institution, and

b. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information for each therapeutic radiation machine for inspection by the agency:

a. Report of acceptance testing;

b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;

c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;

d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Form of records. Rescinded IAB 4/5/00, effective 5/10/00.

c. Dosimetry equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)*"c"*(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)*"c"*(1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)*"c"*(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)*"a"* and *"b"* to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

a. Equipment requirements.

(1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)*"a"*(1)"1" and 41.3(17)*"a"*(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. Means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)*"a"*(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)*"a"*(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18)*"e"* and protection surveys required by 41.3(16)*"a"*;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18)*"f"*(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18)*"d"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)*"a,"* 41.3(18)*"e,"* and 41.3(18)*"f"* have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)*"e"*(1)"3."

(2) The registrant shall use the dosimetry system described in 41.3(16)*"c"* to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)*"f"*(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)*"c"*(1) to make the periodic quality assurance checks required in 41.3(18)*"f"*(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)*"f"*(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within two weeks of treatment; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check within two weeks of completion.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week;

(7) To satisfy the requirement of 41.3(18)*"f"*(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. Proper operation of the "BEAM-ON," interrupt and termination switches;
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
4. Viewing systems;
5. Aural systems;
6. Electrically operated treatment room door(s) from inside and outside the treatment room;

(8) Emergency power cutoff switches shall be checked for proper operation at intervals not to exceed three months. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(9) The registrant shall promptly repair any system identified in 41.3(18)*"f"*(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)*"f"*(1) and 41.3(18)*"f"*(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or *"action levels"* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;
2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and
3. Use of personnel who do not meet the applicable requirements of this chapter.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. The maximum average glandular dose should be 6 milliGray (0.6 rad) or less for a 2-view examination of the breast. See also: "Dose."

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"Certificate" means the certificate described in 41.6(2)*"a"*(2).

"Certification" means the process of approval of a facility by the FDA or this agency to provide mammography services.

"Clinical image" means a mammogram.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Contact hour" means an hour of training received through direct instruction.

"Continuing education unit" or *"continuing education credit"* means one contact hour of training.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Direct instruction" means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or
2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

"Direct supervision" means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or
2. During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Dose" means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"Exposure" means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 × 10E-4 Coulombs of charge per kilogram of air.

"Facility" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

"FDA" means the Food and Drug Administration.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Image noise." See "Radiographic noise."

"Interpreting physician" means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)*"a."*

"Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

"Laterality" means the designation of either the right or left breast.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means a radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or
2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations.

"Mammography equipment evaluation" means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)*"c."*

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

"Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5)*"a"*(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)*"b."*

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) *Registration and application standards and requirements.*

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency authorization by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for the American College of Radiology (ACR) mammography accreditation. An evaluation report issued by the American College of Radiology meets this requirement.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional authorization. A new facility beginning operation after September 30, 1994, is eligible to apply for a provisional authorization. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional authorization, a facility must meet the requirements of 641—41.6(136C). A provisional authorization shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for a 90-day extension.

c. Withdrawal or denial of mammography authorization.

(1) Mammography authorization may be withdrawn with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the authorization.

(2) The facility shall have opportunity for a hearing in connection with a denial or withdrawal of mammography authorization in accordance with 641—Chapter 173.

(3) An emergency order withdrawing authorization may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's authorization is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 60 days after initial mammography authorization and at least annually thereafter.

f. Determination of the quality of the mammograms produced by facilities. To make the determination each facility will:

(1) Provide at the time of initial registration and at renewal (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with fatty breasts,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with at least 75 percent glandular tissue, and

3. Each mammography examination must have been interpreted as a "normal" examination.

(2) Provide randomly (at least every three years), at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)*"f"*(1).

(3) Have the film returned by the agency for inclusion in the patient's file after quality interpretation by agency radiologists.

(4) Be billed the fee for the quality interpretation as set forth in 641—38.8(1)*"b"*(2).

(5) Be provided with a written explanation of the results of the quality evaluation which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).

g. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Parts 16 and 900 which have an effective date of April 28, 1999. Persons authorized to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

41.6(3) *Mammography personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. Interpreting physicians. All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)*"a"*(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

• Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)*"a"*;

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the three years immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

4. Unless the exemption in 41.6(3)"*a*"(3)"2" applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"*a*"(1) were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period;

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"*a*"(1) were completed, the interpreting physician shall have taught or completed at least 15 category I continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in the interpreting physician's practice; and

3. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

4. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)"*a*"(2)"2" even if the course is taught multiple times during the previous 36 months.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)"*a*" or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)"*a.*" They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)"*a*"(1)"1" and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)"*a*"(1)"4."

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)"*a*"(2)"1" shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or
- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

The interpretations required under 41.6(3)"*a*"(4)"1" shall be done within the six months immediately prior to resuming independent interpretation.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)*"a"*(2)"2" shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Prior to April 28, 1999, have qualified as a radiologic technologist under 41.6(3)*"b"* or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)*"b"*; and

3. At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography examinations; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)*"b"*(3)"1" even if the course is taught multiple times during the previous 36 months.

3. At least 6 of the continuing education units required in this subrule shall be related to each mammographic modality used by the technologist.

4. Requalification. Radiologic technologists who fail to meet the continuing education requirements of 41.6(3)*"b"*(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous three years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

5. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)*"b"*(2)"3," the technologist shall have at least 8 hours of continuing education units in the new modality.

(4) Continuing experience requirements.

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) and (2) were completed or October 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)"*c*"(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and
- Have experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"*c*"(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during the physicist's surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of this subrule were completed or April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

3. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under this subrule, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) *Obtaining and preserving records.*

a. The facility of the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

(1) The date the mammography procedure was performed.

(2) The date of the interpretation.

(3) The name of the interpreting physician.

(4) The name of the patient and an additional patient identifier.

(5) A description of the procedures performed.

(6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Overall Final Assessment" with findings classified in one of the following categories or an approved equivalent:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. In cases where no final assessment category can be assigned due to incomplete workup, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service or not less than ten years, if no additional mammograms of the patient are performed.

(3) If the facility should cease to exist before the end of the 60-month period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)*"e"*(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4)*"b,"* to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)*"e"* through *"k."*

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

(3) Output reproducibility and linearity.

(4) Automatic exposure control reproducibility and linearity.

(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammographic facility shall be the ability to observe the image of four 0.75-mm fibriles, three 0.32-mm specks, and three 0.75-mm masses from an ACR-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

(1) Processor performance shall be accomplished daily before processing patient films.

(2) Image quality shall be monitored at least monthly with a phantom and every time the unit is altered including the replacement of parts.

(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 mrad (millirad) for film/screen units with no grids, or 300 mrad for film/screen units with grids.

(2) The monitoring results shall be compared routinely to the standards of image quality in Appendix I. If the results fall outside the acceptable range, the test shall be repeated. If the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted.

h. Retake analysis program.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be within plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.
4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. A compression force of at least 25 pounds (111 newtons) for 15 seconds shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.
- After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.
- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. On and after October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.
- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.
- Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

• The system shall be capable of producing a minimum output of 513 milliRoentgen (mR) per second (4.5 mGy air kerma per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions, shall be capable of producing a minimum output of 800 mR per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

• The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

• An override capability to allow maintenance of compression;

• A continuous display of the override status; and

• A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)*"k"*(5)"6."

(7) Use of test results.

1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside of the action limits, the source of the problem shall be identified, and corrective actions shall be taken:

• Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)*"k"*(1), (2), (4)"1" to (4)"3," (5)"6," and (6);

• Within 30 days of the test date for all other tests described in 41.6(5)*"k."*

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"h."*

2. The results of all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through (7), as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Find adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6)*"i"*(6) and (7).

(4) Except as provided in 41.6(6)*"i"*(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans.

(1) A phantom image shall be produced, processed, and evaluated after each relocation.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

41.6(7) *Safety standards for mammography equipment.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to measure their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 41.6(136C)—APPENDIX I

Rescinded IAB 4/5/00, effective 5/10/00

RULE 41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

	Mo/Mo Target Filter X-Ray Voltage (kVp)											W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.

641—41.7(136C) X-ray machines used for mammographically guided breast biopsy.

41.7(1) *Definitions.* In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)*"a"* or 41.7(3)*"c"*) are working together in consultation and in performing mammographically guided breast biopsies with a common goal of the patient's benefit.

"Mammographically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) *Registration and application standards and requirements.*

a. Each radiation machine used to perform mammographically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform mammographically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The mammographically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform mammographically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire mammographically guided breast biopsy system is evaluated annually by a radiation physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Withdrawal or denial of authorization.

(1) Authorization may be withdrawn with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial or withdrawal of authorization.

(3) An emergency order withdrawing authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 60 days after initial authorization and at least annually thereafter.

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing mammographically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)*"b."*

2. Shall have performed at least 12 mammographically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on image-guided breast biopsies under a physician who is qualified under 41.6(3)*"b"* and has performed at least 24 mammographically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME in image-guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in "2" above and be experienced in recommendations for biopsy and lesion identification at time of biopsy.

5. Shall be responsible for oversight of all quality control and quality assurance activities.

6. Shall be responsible for the supervision of the radiologic technologist and the medical physicist.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographically guided breast biopsies per year or requalify as specified above in 41.7(3)*"a"*(1).

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must have at least three hours of Category 1 CME in mammographically guided breast biopsy which includes instruction on triangulation for lesion location.

2. Must have performed at least 12 mammographically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on mammographically guided breast biopsy procedures under a physician who is both qualified to interpret mammography according to 41.6(3)*"b"* and has performed at least 24 mammographically guided breast biopsies.

3. Shall be responsible for postbiopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

c. Requirements for a radiologist performing mammographically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)*"b."*

2. Initially, must have at least three hours of Category 1 CME in mammographically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 mammographically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on mammographically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)*"b"* and has performed at least 24 mammographically guided breast biopsies.

5. Must be responsible for mammographic interpretation.
6. Must be responsible for patient selection.
7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).
8. Must be responsible for the oversight of all quality control.
9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.
10. Must be responsible for postbiopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.
2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years which includes postbiopsy management of the patient.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing mammographically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must have evaluated at least 480 mammograms per year in the prior two years in consultation with a physician who is qualified according to 41.6(3)*"b."*
2. Initially, must have at least 15 hours of Category 1 CME in mammographically guided breast imaging and biopsy or three years' experience having performed at least 36 image-guided breast biopsies.
3. Must have four hours of Category 1 CME in medical radiation physics.
4. Must have performed at least 12 mammographically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on mammographically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)*"b"* and has performed at least 24 image-guided breast biopsies.
5. Must be responsible for patient selection.
6. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies, cancers found, benign lesions, biopsies needing repeat and complications).
7. Must be responsible for oversight of all quality control.
8. Must be responsible for the supervision of the radiologic technologist and the medical physicist.
9. Must be responsible for postbiopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms per year in consultation with a physician who is qualified according to 41.6(3)*"b."*
2. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.
3. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

41.7(4) *Medical physicist.*

a. Must be qualified according to 41.6(3)*"c."*

b. Must meet the following initial requirements:

(1) Prior to July 1, 1998, have performed three hands-on mammographically guided breast biopsy physics surveys; or one hands-on mammographically guided breast biopsy physics survey under the guidance of a medical physicist qualified through 41.7(4)*"a"* and 41.7(4)*"b."*

(2) On or after July 1, 1998, have one hands-on image-guided breast biopsy physics survey under the guidance of a medical physicist qualified to perform mammographically guided breast biopsy physics surveys. Have at least one mammographically guided breast biopsy physics survey per year after the initial qualifications are met; and three hours of continuing education in mammographically guided breast biopsy physics every three years after the initial qualifications are met.

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"d."*

b. Must meet the following initial requirements:

(1) Five hands-on procedures on patients under the supervision of a qualified physician or technologist.

(2) Three hours of continuing education in mammographically guided breast biopsy.

c. Thereafter, an average of at least 12 mammographically guided breast biopsies per year after initial qualifications are met.

d. Three hours of continuing education in mammographically guided breast biopsy every 3 years after initial qualifications are met.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to image-guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified radiation physicist who is capable of establishing and conducting the program.

c. Under the direction of the supervising physician, the radiation physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, at least annually, to include:

1. Evaluation of biopsy unit assembly.
2. Evaluation of focal spot.
3. kVp accuracy/reproducibility.
4. Half-value layer measurement.
5. Exposure reproducibility.

6. Breast entrance exposure, average glandular dose.
7. Image quality evaluation.
8. Artifact evaluation.
9. Digital field uniformity.
10. Localization simulation (gelatin phantom) test.
11. Evaluation of the facility's technologist quality control program.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

d. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted).

(2) Visual checklist (weekly).

(3) Phantom image (weekly).

(4) Compression (semiannually).

(5) Processor sensitometry (daily before use with systems utilizing film).

e. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure.

41.7(8) *Equipment standards.*

a. Be specifically designed for mammographically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) Regardless of size or shape, at least 0.09 m^2 (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A detailed description of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.
14. An indication of the frequency of screening and the duration of the entire screening program.

APPENDIX D
QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.
[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.
[c] A constancy check with a field instrument using temperature pressure corrections.
[d] Whichever is greater. Should also be checked after change of light field source.
[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance[a]
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[f] Most wedges' transmission factors are field size and depth dependent.

APPENDIX E
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

These rules are intended to implement Iowa Code chapter 136C.

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◊Two ARCs

641—42.2(136C) General requirements.

42.2(1) *Minimum eligibility requirements.*

a. Graduation from high school or its equivalent.

b. Attainment of 18 years of age.

c. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients or operators.

42.2(2) *Disciplinary grounds and actions.* The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying of fines:

a. Operating as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist without meeting the requirements of this chapter.

b. Allowing any individual excluding a licensed physician to operate as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist if that individual cannot provide proof of certification by the department.

c. Failing to report to the department any individual whom the certificate holder knows is in violation of this rule.

d. Submitting false information in order to obtain certification or renewal certification as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist.

e. Any action that the department determines may jeopardize the public, other staff, or certificate holder's health and safety.

f. Performing procedures not allowed under the individual's current certification.

42.2(3) *Continuing education.*

a. Each individual who is certified under these rules shall, during a two-year period, obtain continuing education credit as follows:

(1) General diagnostic radiographer: 24 clock hours, 1.0 hour must be in radiation protection.

(2) Limited in-hospital diagnostic radiographer: 24 clock hours, 1.0 hour must be in radiation protection.

(3) Limited diagnostic radiographer: 12 clock hours, 1.0 hour must be in radiation protection.

(4) General nuclear medicine technologist: 24 hours total.

1. One clock hour in principles of radiation protection and exposure each year, a total of two hours each two-year period.

2. One clock hour in quality assurance each year, a total of two hours each two-year period.

3. The remaining 20 clock hours of continuing education in each two-year period may be in any other subjects directly related to nuclear medicine and approved by the department.

(5) Limited nuclear medicine technologists: 12 hours total, 1.0 hour must be radiation protection and 1.0 hour must be in quality assurance.

(6) Radiation therapist: proof of 24.0 clock hours of continuing education courses in subjects directly related to radiation therapy.

(7) Simulation therapist: proof of 24.0 clock hours of continuing education courses with at least 12.0 hours directly related to radiation therapy. 12.0 hours may be in specified diagnostic radiography courses.

b. Continuing education course approval.

(1) Thirty days prior to conducting a continuing education course, the sponsoring individual must submit the following:

1. The course objectives.

2. An outline of the course which sets forth the subject, the course content, and the length of the course in clock hours.

3. The instructor's name and short résumé detailing qualifications.

(2) Following its review, the department may, in consultation with or under predetermined guidance of the technical advisory committee, approve, disapprove, or request additional information on the proposed course.

(3) The department may, from time to time, audit the continuing education course to verify the adequacy of program content and delivery.

(4) Courses must be at least one clock hour in length and if lasting more than one hour, will be assigned credit in half-hour increments to the closest half-hour.

c. Continuing education credit will be awarded under provisions of 42.2(3) by the department to individuals:

(1) Who have successfully completed a continuing education course which has been approved by the department.

(2) Who present a department-approved continuing education course to individuals certified in the presenter's field. Credit granted shall be at a rate of two times the amount of time it takes to present the course up to a maximum of 50 percent of the total hours required.

(3) Only once during a two-year period for the same continuing education course.

d. Continuing education must be directly related to the area of practice of the operator attending the program. Twenty-five percent of the total hours required may be in "special category."

e. It is required that proof of receiving continuing education be retained at each individual's place of employment for review by representatives of the department. Proof of continuing education must be maintained for at least three years.

f. All continuing education requirements shall be completed during the two-year period prior to the certification continuing education due date.

g. Late submission of continuing education requirements.

(1) For any individual who completes the required continuing education before the continuing education due date but fails to submit the required proof within 30 days after the continuing education due date, the certification shall be terminated and the renewal fee will not be refunded.

(2) Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

(3) Once certification has been terminated, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must submit proof of continuing education hours and shall submit a late fee as set forth in 641—paragraph 38.8(6)*"c"* in addition to the annual fee set forth in 641—paragraph 38.8(6)*"a"* in order to obtain reinstatement of certification.

42.2(4) *Recertification.*

a. If an individual allows the certification to expire for any reason or if any individual voluntarily terminates certification, the following will apply:

(1) Any individual who wishes to regain certification and makes application within six months of the termination date will be allowed to do so with no additional training or testing required.

(2) Any individual who wishes to regain certification after the six-month period will need to meet the current educational and testing requirements for that particular certification. Proof of possession of a previous certification may satisfy the training portion of this requirement.

(3) Any individual who has not renewed certification for at least five years and wants to regain certification, or who has not applied for certification within five years of the completion date of the original training course, will need to complete a recertification program approved by the department of not less than 24 contact hours for general certifications and 12 contact hours for limited certifications which specifically applies to the area of certification.

b. Recertification programs.

(1) The recertification program must review those basic principles necessary to ensure minimum competency in the certification area and must also include the satisfactory completion of a written examination. Both the program and the examination must acquire prior approval from the department. Courses designed for use in the recertification program will not qualify for continuing education credit for those individuals required to attend in order to recertify.

(2) If no approved programs are available, the department may require attendance for a minimum of 24 contact hours for general certifications and 12 hours for limited certifications at specific continuing education programs. The continuing education must be confined to subjects which apply to the area of certification limitation, if any, and would have to be completed within a specified time period.

c. Exemptions. Any or all of the above-mentioned requirements may be waived for an individual who has been actively employed in the certification area in another state, country, or federal institution or who can prove circumstances above and beyond the norm. These cases will be reviewed on an individual basis and the decision of the department shall be final.

d. Training programs. Any individual submitting a training program to the department for approval must provide the following:

(1) An outline of the didactic and clinical studies to meet the requirements of this subrule.

(2) Proof that the instructor meets the requirements of this rule as a diagnostic radiographer, nuclear medicine technologist, radiation therapist or is a licensed physician trained in the specific area of competence.

(3) A time schedule of the training program.

(4) A description of the mechanism to be used to determine competency.

e. Upon the completion of the training the following must be submitted:

(1) A statement of competency from the trainer.

(2) A statement of permission to allow a representative of the department to comprehensively evaluate whether the individual meets the training standard.

42.2(5) *Fees.* All individuals certified under this rule must pay fees as specified in 641—subrule 38.8(6).

641—42.3(136C) Specific requirements for diagnostic radiographers.

42.3(1) *Training requirements.*

a. General diagnostic radiographer. Successful completion of a Joint Review Committee on Education in Radiologic Technology approved course of study or equivalent to prepare the student to demonstrate competency in the following areas:

(1) Radiation protection of patients and workers, including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical consideration in reducing radiation exposure and frequency of retakes;

(2) Technique and quality control to achieve diagnostic objectives with minimum patient exposure, including X-ray examinations, X-ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;

(3) Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid, and contrast media;

(4) Positioning, including normal and abnormal anatomy and projections;

(5) Radiographic equipment and operator maintenance to include X-ray tubes, grids, standardization of equipment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X-ray control consoles, tilt tables, ancillary equipment, fluoroscopes and electrical and mechanical safety;

(6) Special techniques, including stereo, body section radiography, pelvimetry, image intensification, photo timing and mobile units; and

(7) Clinical experience sufficient to demonstrate competency in the application of the above as specified in the "Standards for an Accredited Education Program in Radiologic Sciences" as adopted by the Joint Review Committee on Education on Radiologic Technology.

b. Limited diagnostic radiographer.

(1) Completion of an approved course of study to prepare the student to demonstrate competency in the following areas:

1. Radiation protection of patients and workers including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical considerations in reducing radiation exposure and frequency of retakes;

2. Technique and quality control to achieve diagnostic objectives with minimum patient exposure to include X-ray examination, X-ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;

3. Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid;

4. Positioning, including normal and abnormal anatomy and projections for the specific category;

5. Radiographic equipment and operator maintenance to include X-ray tubes, grids, standardization of equipment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X-ray control consoles, tilt tables, ancillary equipment, and electrical and mechanical safety;

6. Special techniques limited to those required by the specific category; and

7. Clinical experience sufficient to demonstrate competency in the application of the above as specified by the department. Clinical experience must be directly supervised by a two-year trained general radiographer, licensed physician, chiropractor, or podiatrist who physically observes and critiques the actual X-ray procedures.

8. Permission for a representative of the Iowa department of public health to comprehensively evaluate whether the individual meets the training standard.

c. Limited in-hospital diagnostic radiographer. An individual employed in a diagnostic radiography facility which has a workload of less than 5000 examinations per year and which provides 24-hour service in a hospital will be permitted to apply X-radiation to any part of the human body at that facility if the individual completes a training program recognized by the department, as outlined in 42.1(4)*"b"*(1) and submits a letter from a board-certified or board-eligible radiologist who verifies in writing the specific procedures the individual is competent to perform. The training program must cover the areas outlined in 42.1(4)*"b,"* the anatomy and physiology of the entire body, positioning and techniques relative to the procedures to be performed, and appropriate clinical training which includes all parts of the human body. Training received under this subrule is specific to the facility and must be reevaluated by the department before an individual may transfer to another facility.

c. Any individual, other than a licensed physician, seeking certification as a limited nuclear medicine technologist shall, in addition to the requirements of 42.4(2)*"b,"* successfully complete a written examination approved by the department which includes the subject matter specified in 42.4(2)*"b."*

d. Any individual holding temporary certification must successfully complete an approved examination within one year of the issuance date of the certification.

42.4(4) *Exemptions.*

a. Students enrolled in and participating in an approved program or approved course of study for nuclear medicine technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radioactive material to a human being while under the supervision of a licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa or NRC radioactive materials license.

b. A licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license.

641—42.5(136C) Specific requirements for radiation therapists.

42.5(1) *Specific eligibility requirements.* Each individual shall meet one of the following:

a. Any individual who is registered in radiation therapy with the American Registry of Radiological Technologists in radiation therapy meets the education and testing requirements of this rule.

b. Any individual, other than a licensed physician, who has completed all educational requirements of this rule but has not successfully completed the required examination will be issued temporary certification valid for one year from the date of completion of a training program approved by the department.

42.5(2) *Training requirements.*

a. General radiation therapist. Successful completion of a Joint Committee on Education in Radiologic Technology approved course of study or equivalent designed to prepare the student to demonstrate didactic and clinical competency in radiation therapy including, but not limited to, anatomy, physiology, radiation physics, radiation protection and exposure, quality assurance, radiation oncology treatment techniques, dosimetry, radiation oncology and pathology, radiology, oncologic patient care and management.

b. Limited radiation therapist. Successful completion of a training program approved by the department to prepare the student to demonstrate competency in a specified area only. This includes the simulation therapist. Each program shall include the items in 42.5(2)*"a"* that are specific to the limited area.

c. Graduates of programs recognized by the department in consultation with the professional societies and others as being adequate and appropriate courses of study in radiation therapy technology may be considered to meet the requirements of this subrule.

42.5(3) *Examinations.*

a. Any individual, other than licensed physicians, seeking certification as a radiation therapist shall, in addition to the requirements of 42.5(2), satisfactorily complete a written examination in radiation therapy technology approved by the department. An approved examination is offered by the American Registry of Radiologic Technologists.

b. Any individual certified under these rules and exempted from examination is exempt from examination requirements as long as the initial certification remains in effect.

c. Any individual seeking to perform simulation radiography only must successfully complete an approved examination in either diagnostic radiography or radiation therapy.

d. Any individual holding a temporary certification must successfully complete an approved examination within one year of the date of completion of the training.

42.5(4) *Exemptions.*

a. Students enrolled in and participating in an approved program or approved course of study for radiation therapy technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radiation therapy to a human being while under the supervision of a licensed physician in the state of Iowa. Clinical experience must be directly supervised by a radiation therapist or radiation oncologist who physically observes and critiques the actual radiation therapy procedure.

b. A licensed physician in the state of Iowa.

These rules are intended to implement Iowa Code chapter 136C.

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**Subrule 42.1(4)"*b*"(4) is rescinded two years subsequent to the effective date of rule 42.1(136C).
◊Two or more ARCs.

CHAPTER 45
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

[Prior to 8/5/92, see 641—41.4(136C)]

641—45.1(136C) General requirements for industrial radiography operations.

45.1(1) *Purpose and scope.* The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999.

The provisions of 641—Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

45.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply. As used in this chapter, the following definitions apply:

"Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

"Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X-ray system is intended to:

1. Contain at least that portion of a material being irradiated;
2. Provide radiation attenuation; and
3. Exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

"Certifiable cabinet X-ray system" means an existing uncertified X-ray system that has been modified to meet certification requirements specified in 21 CFR 1020.40.

"Certified cabinet X-ray system" means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Certifying entity" means an independent certifying organization meeting the requirements in Appendix E of this chapter or Agreement State meeting the requirements of Appendix E or the requirements of Appendix A in 10 CFR Part 34.

"Collimator" means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Crank-out device" means the cable, protective sheath, and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded-room radiography.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

"GED" means general educational development.

"Guide tube (projection sheath)" means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

"I.D. card" means the document issued by the agency, another Agreement State, a licensing state, or third-party certification to industrial radiographers following completion of requirements stated in 45.1(10)*"b."*

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix E to this chapter.

"Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Lock-out survey" means a radiation survey performed to verify that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or when securing the radiographic exposure device or source changer.

"Minimal threat" means that during the operations of electronic devices capable of generating or emitting fields of radiation:

a. No deliberate exposure of an individual occurs;

b. The radiation is not emitted in an open beam configuration; and

c. No known physical injury to an individual has occurred.

"Offshore" means within the territorial waters of the United States.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Platform radiography" means industrial radiography performed on an offshore platform or other structure.

"Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiation safety officer" means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 45.1(10)*"d."*

"Radiographer" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)*"b,"* who performs or personally supervises industrial radiographic operations, and is responsible to the licensee or registrant for ensuring compliance with the requirement of these rules and all license and certificate of registration conditions.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographer trainee" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)*"a"* and who uses sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.

"Radiographer trainer (instructor)" means any individual who instructs and supervises radiographer trainees during on-the-job training and who meets the requirements of 45.1(10)*"c."*

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

"Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"Radiographic personnel" means any radiographer or radiographer trainee.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source container" means a shielded device in which sealed sources are secured, transported, and stored.

"Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a shielded device in which sealed sources are secured, transported, and stored.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

"Trainee status card" means the document issued by the agency following completion of the requirements of 45.1(10)*"a"*(1) and (2).

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

45.1(3) *Exemptions.*

a. Uses of certified and certifiable cabinet X-ray systems designed to exclude individuals are exempt from the requirements of this chapter, except for the requirements of 45.2(6)*"b"* and *"c."*

b. Industrial uses of lixiscopes are exempt from the requirements in this chapter.

c. Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with 641—subrule 38.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

45.1(4) *Receipt, transfer, and disposal of sources of radiation.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date the individual made the record, the radionuclide, number of curies, and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for agency inspection until disposal is authorized by the agency.

45.1(5) *Radiation survey instruments.*

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and 641—subrule 40.36(1). Instrumentation required by this subrule shall have a range such that 2 millirems (0.02 millisievert) per hour through 1 rem (0.01 sievert) per hour can be measured.

b. Notwithstanding the requirements of 641—subrule 40.36(2) each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed six months and after each instrument servicing;

(2) Such that accuracy within plus or minus 20 percent can be demonstrated;

(3) At 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at 3 points between 2 and 1000 mrem per hour for digital instruments; and

(4) By a person licensed or registered by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission to perform such service.

c. Records of these calibrations shall be maintained for three years after the calibration date for inspection by the agency.

d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

45.1(6) *Quarterly inventory.* Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed by the licensee. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

45.1(7) *Utilization logs.*

a. Each licensee shall maintain current logs of the use of each sealed source. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each radiographic exposure device containing a sealed source, and each sealed source;

(2) The identity of the radiographer using the sealed source;

(3) Locations where each sealed source is used; and

(4) The date(s) each sealed source is removed from storage and returned to storage.

b. Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each source of radiation;

(2) The identity of the radiographer using the source of radiation;

(3) The date(s) each source of radiation is energized or used and the number of exposures made.

c. Utilization logs may be kept on IDPH Form 588-2693, Utilization Log, or on clear, legible records containing all the information required by 45.1(7)*"a"* or *"b."* Copies of utilization logs shall be maintained for agency inspection for three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

45.1(8) *Inspection and maintenance.*

a. Each licensee or registrant shall ensure that visual and operability checks for obvious defects, proper working order, adequate shielding, and required labeling of radiation machines, radiographic exposure devices, storage containers, and source changers, and survey instruments are performed prior to each day or shift of use.

b. Each licensee or registrant shall conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the agency for two years from the date of the recorded event. This program shall cover, as a minimum, the items in Appendix B.

c. If any inspection conducted pursuant to 45.1(8)*"a"* or *"b"* reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.

45.1(9) *Permanent radiographic installations.* Permanent radiographic installations having high radiation area entrance controls of the type described in 641—paragraphs 40.42(1)*"b"* and *"c"* shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for three years from the date of the event.

45.1(10) *Training and testing for radiographic personnel.*

a. Radiographer trainee requirements. No licensee or registrant shall permit any individual to act as a radiographer trainee, as defined in this chapter, until:

(1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:

1. The subjects outlined in Appendix A, presented in a course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

2. The rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40;
3. The appropriate conditions of license(s) or certificate(s) of registration; and
4. The licensee's or registrant's operating and emergency procedures.

(2) The individual possesses a current agency-issued trainee status card issued after completion of 45.1(10)"*a*"(1). Trainee status will be granted only once for each individual and is valid for no longer than two years.

b. Radiographer requirements. No licensee or registrant shall permit any individual to act as a radiographer:

(1) Until it has been documented to the agency that such individual:

1. Has completed the requirements of 45.1(10)"*a*"(1);

2. Has completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines, or both. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (three months or 480 hours). Active participation does not include safety meetings or classroom training;

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments;

(2) Unless the individual has successfully completed within the last five years the appropriate agency-administered examination prescribed in 45.1(10)"*f*"(2) or equivalent examination; and

(3) Unless the individual possesses a current I.D. card.

c. Radiographer trainer. No individual shall act as a radiographer trainer unless such individual:

(1) Has met the requirements of 45.1(10)"*a*"(1) and "*b*";

(2) Has one year of documented experience as an industrial radiographer; and

(3) Is named on the specific license or certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer, or

(4) Possesses a valid radiographer trainer card issued by the agency.

d. Radiation safety officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's program.

(1) A radiation safety officer (RSO) shall be designated for every industrial radiography license and certificate of registration issued by the agency.

(2) The RSO's qualifications shall include:

1. Possession of a high school diploma or a certificate of high school equivalency based on the GED test;

2. Completion of the training and testing requirements of 45.1(10)"*a*"(1) and 45.1(10)"*b*"(1)"3," (2), and (3); and

3. Two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.

(3) The specific duties of the RSO include, but are not limited to, the following:

1. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

2. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

3. To ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

4. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

5. To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

6. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

7. To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

8. To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

9. To maintain records as required by these rules (see Appendix C);

10. To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

11. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.2(3), and 45.3(6)*"b"*; and

12. To ensure that personnel are complying with these rules, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.

e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10)*"a"* and *"b"* are met for all industrial radiographic personnel. Records shall be kept on IDPH Form 588-2692 or on clear, legible records containing all the information required by IDPH Form 588-2692. Records shall be maintained until disposal is authorized by the agency.

f. Applications and examinations.

(1) Application.

1. An application for taking the examination shall be on forms prescribed and furnished by the agency along with the fee required in 641—38.8(3).

2. An individual whose I.D. card has been suspended or revoked shall obtain prior approval from the agency to apply to take the examination.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at such times and places as the agency shall determine. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will emphasize the applicant's ability to safely use sources of radiation and related equipment and the applicant's knowledge of these rules.

2. A candidate failing an examination may apply for reexamination in accordance with 45.1(10)*"f"*(1) and will be reexamined. A candidate shall not retake the same version of the agency-administered examination.

3. The examination will be held at locations designated by the agency. The examination shall normally be offered quarterly. Dates, times, and locations of the examinations will be provided by the agency.

4. The examination will be in the English language.

5. To take the examination, an individual shall have a picture identification card (such as an Iowa driver's license) at the time of the examination.

6. Calculators will be permitted during the examination; however, calculators or computers with preprogrammed data or formulas, including exposure calculations, will not be permitted.

7. The examination will be a "closed book" examination.

8. Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to the administration is prohibited.

9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual may resubmit an application and an additional examination fee to take the examination not earlier than three months later.

10. The names and scores of individuals taking the examination shall be a public record.

g. Identification procedures.

(1) I.D. card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10)*"b"* and the examination prescribed in 45.1(10)*"f"*(2) or an equivalent examination. Certification by a certifying entity in accordance with 10 CFR 34.43(a)(1) meets the examination requirements of 45.1(10)*"f"*(2) but not the requirements of 45.1(10)*"b"*(1).

2. Each person's I.D. card shall contain the person's photograph.

3. The I.D. card remains the property of the state of Iowa and may be revoked or suspended under the provisions of 45.1(10)*"h."*

4. Any individual who wishes to replace the I.D. card shall submit to the agency a written request for a replacement I.D. card, stating the reason a replacement I.D. card is needed and the fee required in 641—subrule 38.8(3). The individual shall maintain in possession a copy of the request while performing industrial radiographic operations until a replacement I.D. card is received from the agency.

(2) Expiration of I.D. card. Each I.D. card expires at the end of the day, in the month and year stated on the I.D. card.

(3) Renewal of I.D. card.

1. Applications for examination to renew an I.D. card shall be filed in accordance with 45.1(10)*"f"*(1).

2. The examination for renewal of an I.D. card shall be administered in accordance with 45.1(10)*"f"*(2).

3. A renewed I.D. card shall be issued in accordance with 45.1(10)*"g"*(1).

h. Revocation or suspension of an I.D. card.

(1) Any radiographer who violates these rules may be required to show cause at a formal hearing why the I.D. card should not be revoked or suspended.

(2) When an agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending the I.D. card, the industrial radiographer shall surrender the I.D. card to the agency until such time as the order is changed or the suspension expires.

(3) An agency's inspector may, in certain instances, confiscate any radiographer's I.D. card on the spot while conducting an inspection or investigation. If the inspector determines that the activities being conducted by the radiographer are significant enough to be classified as severity I, II, or III, as specified in 641—38.5(136C), and after obtaining the approval of agency management, the inspector may take any radiographer's I.D. card. The agency will then issue a cease and desist order to the radiographer's employer, forward the I.D. card(s) to the issuing entity, and notify the U.S. Nuclear Regulatory Commission and other agreement states.

i. Exemptions. Any person using a source of radiation to determine the presence of explosives in a package or the authenticity of a piece of art is exempt from the provisions of 45.1(10)*"a"* to *"h."*

45.1(11) *Internal audits.* Except as provided in 45.1(11)*"c,"* the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer trainee to ensure that these rules, license requirements, and the licensee's or registrant's operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and radiographer trainee during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or radiographer trainee has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or radiographer trainee must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can next participate in a radiographic operation.

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

d. Records of audits shall be maintained by the licensee or registrant for agency inspection for three years from the date of the audit.

45.1(12) *Personnel monitoring control.*

a. The personnel monitoring program shall meet the applicable requirements of 641—Chapter 40.

b. When performing industrial radiographic operations:

(1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainee, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically stimulated device (OSD) or a thermoluminescent dosimeter (TLD). For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

(2) Pocket dosimeters or electronic personal dosimeters shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 milliroentgens.

(3) Pocket dosimeters or electronic personal dosimeters shall be recharged at the start of each work shift.

(4) Pocket dosimeters or electronic personal dosimeters shall be read and exposures recorded at least once daily, at the end of each work shift, and before each recharging.

(5) If an individual's pocket dosimeter is discharged beyond its range (i.e., goes "off scale"), or if the electronic personal dosimeter reads greater than 200 millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each film badge, OSD or TLD shall be assigned to and worn by only one individual.

(7) Film badges, OSDs and TLDs must be replaced at least monthly. After replacement, each film badge, OSD or TLD must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier.

(8) If a film badge, OSD or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge, OSD or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge, OSD or TLD.

c. Records of pocket dosimeter readings of personnel exposures shall be maintained for two years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained until the agency authorizes disposal.

d. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for two years from the date of the event.

e. Reports received from the film badge or TLD processor shall be kept for inspection by the agency until the agency authorizes disposition.

f. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift. Records of alarm function checks shall be maintained for two years by the licensee or registrant for agency inspection;

(2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of the alarming ratemeter calibrations shall be maintained for two years by the licensee or registrant for agency inspection.

45.1(13) *Supervision of radiographer trainee.* Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor. The personal supervision must include:

a. The radiographer's physical presence at the site where the source(s) of radiation is being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the trainee's performance of the operations referred to in this subrule.

45.1(14) *Access control.*

a. During each industrial radiographic operation, a radiographer shall maintain visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area or high radiation area, except:

(1) Where the high radiation area is equipped with a control device or an alarm system as described in 641—subrule 40.42(1); or

(2) Where the high radiation area is locked to protect against unauthorized or accidental entry.

b. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

45.1(15) *Posting.*

a. Notwithstanding any provisions in 641—subrule 40.62(1) areas in which radiography is being performed shall be conspicuously posted as required by 641—subrules 40.61(1) and 40.61(2).

b. Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate areas in accordance with 641—subrule 40.26(1) and to help prevent unauthorized entry.

641—45.3(136C) Radiation safety requirements for use of sealed sources of radiation in industrial radiography.

45.3(1) *Limits on external radiation levels from storage containers and source changers.* The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisievert) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

45.3(2) *Locking of sources of radiation.*

a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental removal or exposure of a sealed source and shall be kept locked and, if applicable, the key removed, at all times except when under the direct surveillance of a radiographer or radiographer trainee, or as may be otherwise authorized pursuant to 45.3(6). Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer trainee.

b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to ensure that the sealed source is in the shielded position.

c. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 45.3(7)*"b."*

45.3(3) *Storage precautions.*

a. Locked radiographic exposure devices, source changers, transport packages, and storage containers shall be physically secured to prevent tampering, accidental loss, or removal by unauthorized personnel and stored to minimize danger from explosion or fire.

b. Radiographic exposure devices, source changers, or storage containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with 45.3(3)*"c,"* and if the vehicle does not constitute a permanent storage location as described in 45.1(9).

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee;

(2) Industrial radiographic services are advertised for or from the location;

(3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

45.3(4) *Performance requirements for radiography equipment.* Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, and from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone (212)642-4900. Copies of the document are available for inspection at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.

b. In addition to the requirements specified in paragraph *"a"* of this subrule, the following requirements apply to radiographic exposure devices and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and the date on which this activity was measured;
3. Model number and serial number of the sealed source;
4. Manufacturer of the sealed source; and
5. Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 641—39.5(136C).

(3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in paragraphs *"a"* and *"b"* of this subrule, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for radiographic operation or source changing:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter;

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with safe operation of the exposure device or associated equipment;

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

(6) Guide tubes must be used when moving the source out of the device;

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations;

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980;

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, must comply with the requirements of this subrule.

e. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this subrule.

f. Notwithstanding the requirements of 45.3(4)*"a,"* equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

g. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component pursuant to the above-referenced standard.

45.3(5) *Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.*

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state.

b. Leak testing.

(1) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6-month period prior to the transfer, the sealed source shall not be put into use until tested.

(2) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration must be tested for DU contamination at intervals not to exceed 12 months. Should the leak test reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination if the interval of storage exceeded 12 months.

c. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 641—subparagraph 39.4(27)*"e"*(5). Records of leak test results shall be kept in units of microcuries (becquerels) and maintained for inspection by the agency for six months after the next required leak test is performed or until the sealed source is transferred or disposed.

d. Any test conducted pursuant to 45.3(5)*"b"* and *"c"* which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with rules of the agency. Within five days after obtaining results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.

e. Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

45.3(6) *Operating and emergency procedures.*

a. The licensee's operating and emergency procedures shall include instructions in at least the following:

(1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 641—Chapter 40;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing sources of radiation;

(5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

(6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

(7) Minimizing exposure of individuals in the event of an accident;

(8) The procedure for notifying proper personnel in the event of an accident;

(9) Maintenance of records;

(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines;

(11) The procedure(s) for identifying and reporting defects and noncompliance in 10 CFR Part 21; and

(12) Source recovery procedure if the licensee will perform source recovery.

b. Rescinded IAB 4/8/98, effective 7/1/98.

c. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer trainee. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Except for the situation of a radiographer trainer with a trainee, radiography shall not be performed if only one qualified individual is present.

d. Collimators shall be used in industrial radiographic operations which use crank-out devices except when physically impossible.

e. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

45.3(7) *Radiation surveys and survey records.*

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and for each exposure device used at each site where radiographic exposures are made.

b. A survey with a calibrated and operable radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube and collimator. The survey required by this subrule must be done before exchanging films, repositioning the exposure head or dismantling the equipment.

c. (1) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 641—40.61(136C), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (i.e., with the sealed source in the exposed position) to confirm that 641—40.61(136C) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

(2) Each time the exposure device is relocated or the exposed position of the sealed source is changed, the requirements of 45.3(7)*"c"*(1) shall be met.

(3) The requirements of 45.3(7)*"c"*(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure include, but are not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

d. A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be made to determine that each sealed source is in its shielded position before securing the radiographic exposure device or source changer.

e. The sealed source shall be secured in its shielded position by locking the radiographic exposure device or source changer each time the sealed source is returned to its shielded position.

f. Each radiographic exposure device and source changer shall be locked and the key removed from any keyed lock prior to being moved or transported from one location to another and also prior to being stored at a given location.

g. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

h. Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 641—40.15(136C). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

i. A survey meeting the requirements of 45.3(7)*"b"* shall be performed on the radiographic exposure device and the source changer after every sealed source exchange. A survey shall be made of the storage area as defined in 641—45.2(136C) whenever a radiographic exposure device is being placed in storage.

j. Records shall be kept of the surveys required by 45.3(7)*"c," "d," "g," "h,"* and *"i."* Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.3(8) *Requirements for enclosed radiography.*

a. Systems for enclosed radiography, including shielded-room radiography designed to allow admittance of individuals shall comply with all applicable requirements of this chapter.

b. Procedures shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with 45.1(9)*"b."*

45.3(9) *Underwater, offshore platform, and lay-barge radiography.*

a. Underwater, offshore platform, or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 641—paragraph 39.4(27)*"e."*

b. In addition to the other rules of this chapter, the following rules apply to the performance of lay-barge or offshore platform radiography:

(1) Cobalt-60 sources with activities in excess of 20 curies (nominal) and iridium-192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of lay-barge or offshore platform industrial radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay-barge or offshore platforms.

45.3(10) *Prohibitions.* Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

45.3(11) *Licensing for industrial radiographic operations.* Rescinded IAB 4/5/00, effective 5/10/00.

641—45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

45.4(1) *Purpose and scope.*

a. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C). The requirements of 45.1(10) do not apply.

45.4(2) *Definitions.* For purposes of this subrule, definitions in 641—Chapters 38 and 40 and subrule 45.1(2) may also apply. As used in this rule, the following definitions apply:

"Cold pasteurization" means the process of using radiation for destroying disease-causing microorganisms in commercial products.

"Self-shielded particle accelerator" means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

"Shielded facility" means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40, or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

45.4(3) *Registration or license requirements.* No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C) and the following requirements:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39.

b. For accelerator facilities required to be licensed in accordance with 45.4(3), those operations that would require personnel monitoring, pursuant to 641—40.37(136C), due to the presence of radioactive material, shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance as well as routine operations.

45.4(4) *General requirements for the issuance of a registration or license for particle accelerators.* Along with the requirements of 641—39.1(136C) to 39.4(136C), an application for use of a particle accelerator will be approved only if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 45.4(4);

d. The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;

e. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has an adequate training program for operators of particle accelerators.

45.4(5) *Personnel monitoring.* In addition to the requirements of 641—Chapter 40, personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area; and

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

45.4(6) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

45.4(11) *Radiation monitoring requirements.*

a. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

b. Accelerator facilities registered pursuant to 45.4(3)*"a"* shall survey with a radiation detection instrument at intervals not to exceed three months. Records of this survey shall be maintained for agency review for three years.

c. Accelerator facilities registered pursuant to 45.4(3)*"a"* shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

d. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage. In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator. Records of this survey shall be maintained for agency review for three years.

e. Accelerator facilities registered pursuant to 45.4(3)*"a"* shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

f. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

g. Upon installation, all area monitoring equipment shall be tested to assure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

h. Whenever applicable, accelerator facilities registered pursuant to 45.4(3)*"a"* shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

i. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert who is acceptable to the agency.

j. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

45.4(12) *Radiation safety officer.*

a. Each registrant shall appoint a radiation safety officer that meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents two years of radiation protection experience.

b. The specific duties of the RSO include, but are not limited to, the following:

(1) To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

(2) To oversee and approve all phases of the training program for accelerator operators so that appropriate and effective radiation protection practices are taught;

(3) To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

(7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

(9) To maintain records as required by these rules;

(10) To ensure the proper storing, labeling, and use of the accelerator;

(11) To ensure that inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.4(10)*"c"*; and

(12) To ensure that personnel are complying with these rules and the operating and emergency procedures of the registrant.

641—45.5(136C) Radiation safety requirements for analytical X-ray equipment.

45.5(1) *Purpose and scope.* This rule provides special requirements for analytical X-ray equipment. The requirements of this rule are in addition to, and not in substitution for, 641—Chapters 38, 39, and 40. The requirements of rules 641—45.1(136C) to 641—45.4(136C) do not apply.

45.5(2) *Definitions.* For the purpose of this subrule, definitions in 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

"Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

"Analytical X-ray system" means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local components" means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

"Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

45.5(3) *Equipment requirements.*

a. Safety device. A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

CHAPTER 45—APPENDIX E

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of radiation safety.
   A. Characteristics of radiation.
   B. Units of radiation dose and quantity of radioactivity.
   C. Significance of radiation dose.
      1. Radiation protection standards.
      2. Biological effects of radiation dose.
   D. Levels of radiation from sources of radiation.
   E. Methods of minimizing radiation dose.
      1. Working time.
      2. Working distances.
      3. Shielding.
   F. Radiation safety practices including prevention of contamination and methods of decontamination.

II. Radiation detection instrumentation to be used.
   A. Use of radiation survey instruments.
      1. Operation.
      2. Calibration.
      3. Limitations.
   B. Survey techniques.
   C. Use of personnel monitoring equipment.

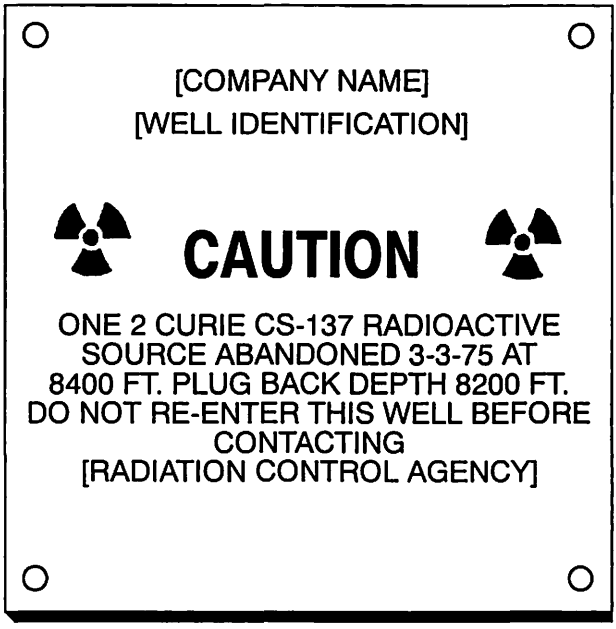
III. Equipment to be used.
   A. Handling equipment.
   B. Sources of radiation.
   C. Storage and control of equipment.
   D. Operation and control of equipment.

IV. The requirements of pertinent federal and state regulations.

V. The licensee's or registrant's written operating and emergency procedures.

VI. The licensee's or registrant's record-keeping procedures.

CHAPTER 45—APPENDIX F
EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE



The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., ½-inch and ¼-inch letter size, respectively.

These rules are intended to implement Iowa Code chapters 136B and 136C.

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CHAPTER 46
MINIMUM REQUIREMENTS FOR TANNING FACILITIES

641—46.1(136D) Purpose and scope. This chapter provides for the permitting and regulation of tanning facilities and devices used for the purpose of tanning human skin through the application of ultraviolet radiation. This includes, but is not limited to, public and private businesses, hotels, motels, apartments, condominiums, and health and country clubs.

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of May 10, 2000.

These rules stipulate minimum safety requirements relating to the operation of tanning devices; procedures for obtaining a permit; qualifications for tanning facility operators; and procedures for health departments to provide for the inspection of tanning facilities and enforcement of these rules. Tanning facilities which are in compliance with these rules are not relieved from the requirements of any other federal and state regulations or local ordinances.

641—46.2(136D) Definitions.

"Board of health" means a county, city, or district board of health that has a 28E agreement with the Iowa department of public health to perform inspections under this chapter.

"Cleansing" means to remove soil, dirt, oils or other residues from the surface of the tanning unit which may come into contact with the skin.

"Cleansing agent" means a substance capable of producing the effect of "cleansing." These agents shall not adversely affect the equipment or the health of the consumer and shall be acceptable to the department or board of health.

"Consumer" means any member of the public who is provided access to a tanning facility in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning facility as a condition or benefit of membership or access.

"Department" means the Iowa department of public health.

"Director" means the director of public health or the director's designee.

"Exposure position" means any position, distance, orientation, or location relative to the radiation surfaces of a tanning device at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.

"Formal training" means a course of instruction approved by the department for operators of tanning facilities.

"Health care professional" means an individual, licensed by the state of Iowa, who has received formal medical training in the use of phototherapy.

"Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, orders, requirements, and conditions of these rules.

"Manufacturer's recommendations" means written guidelines established by a manufacturer and approved by the U.S. Food and Drug Administration for the installation and operation of the manufacturer's equipment.

"Operator" means an individual designated to control operation of the tanning facility and to instruct and assist the consumer in the proper operation of the tanning devices.

"Permit" or *"permit to operate"* means a document issued by the department which authorizes a person to operate a tanning facility in Iowa.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

"Phototherapy device" means a piece of equipment that emits ultraviolet radiation and is used by a health care professional in the treatment of disease.

"Tanning device" means any equipment that emits electromagnetic radiation with wavelengths in air between 200 and 400 nanometers and that is used for tanning of human skin, such as sunlamps, tanning booths, or tanning beds. The terms also include any accompanying equipment such as protective eyewear, timers, and handrails.

"Tanning facility" means a place that provides access to tanning devices for compensation.

"Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between 200 and 400 nanometers.

641—46.3(136D) Exemptions. The department may, upon application or upon its own initiative, grant exemptions from the requirements of these rules as long as it will not result in undue hazard to public health and safety. The following categories of devices are exempt from the provisions of this chapter:

46.3(1) *Other purposes.* Devices intended for purposes other than the deliberate exposure of human skin to ultraviolet radiation which produce or emit ultraviolet radiation incidental to their proper operation.

46.3(2) *Personal use.* Tanning devices which are limited exclusively to personal use by an individual and this individual's immediate family. Multiple ownership of the device by persons for personal use only does not qualify it for the "personal use only" exemption.

46.3(3) *Phototherapy devices.* Phototherapy devices used by a properly trained health care professional in the treatment of disease.

641—46.4(136D) Permits and fees.

46.4(1) *Permit to operate.* No tanning facility shall be operated in the state without having a permit to operate issued by the department.

46.4(2) *Application requirements for permit.* Each person acquiring or establishing a tanning facility shall:

a. Apply for a permit prior to beginning operation. The application shall be completed on forms provided by the department or board of health and shall contain all information required by the form and accompanying instructions. A nonrefundable application fee of $5 shall be remitted with the application.

b. A $15 returned check fee will be charged for each check returned for insufficient funds.

c. The permit holder shall notify the department in writing within 30 days of any changes, additions, or deletions to the initial or renewal application as appropriate. This request does not apply to changes involving replacement of components in tanning equipment.

46.4(3) *Expiration of permit.* Except as provided in 46.4(4)*"b,"* each permit shall expire at the end of the specified day in the month and year stated therein.

46.4(4) *Renewal of permit.*

a. Permits shall be renewed annually upon acceptance of a renewal application provided by the department and upon receipt of the renewal fee of $5.

b. If application has been filed prior to the expiration date of the existing permit, the existing permit shall not expire until the application status has been finally determined by the department.

c. A $25 fee will be charged per month for failure to pay annual permit fees starting the month of expiration of the facility's permit to operate. This fee is added to the annual fee not paid.

46.4(5) *Transfer or termination of permit.*

a. No permit shall be transferable from one person to another or from one tanning facility to another.

b. A permit shall be returned to the department or board of health if the facility ceases business or otherwise ceases on a permanent basis or changes ownership.

46.4(6) *Denial, revocation, or termination of permit.*

a. The department may deny, suspend or revoke a permit applied for or issued pursuant to this chapter for any of the following reasons:

(1) Submission of false statements in the application for a permit or in any statement of fact required by provisions of this chapter;

(2) Because of conditions revealed by the application or any report, record, inspection or other means which would warrant the department to refuse to grant a permit on an original application;

(3) Operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety;

(4) Failure to allow authorized representatives of the department or board of health to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this chapter, conditions of the permit or an order of the department or board of health;

(5) Failure to pay fees or costs required in rule 46.4(136D);

(6) Violation of any of the provisions of this chapter or of Iowa Code chapter 136D.

b. Except in cases where public health and safety require otherwise, prior to the institution of proceedings for suspension or revocation of a permit, the department or board of health shall:

(1) Call to the attention of the permit holder, in writing, the facts or conduct which may warrant such actions, and

(2) Provide opportunity for the permit holder to demonstrate or achieve compliance with all lawful requirements.

c. Any person aggrieved by a decision by the department to deny a permit or to suspend or revoke a permit after issuance may request a hearing under procedures established by the department.

46.4(7) *Inspections.*

a. Inspections shall be conducted annually.

b. Inspection cost.

(1) An inspection cost of $33 per tanning device shall be billed to the permit holder up to a maximum of $330 per facility.

(2) Inspection costs shall be due upon receipt of payment due. When the tanning facility is located within a contracted area of a board of health, the costs billed will be paid to the contracted board of health or its designee.

(3) Inspection costs not received within 45 days of the date of billing will be assessed a $25 penalty for each month or fraction thereof that the bill is delinquent.

c. Inspections shall include the following areas: proper operation and maintenance of devices, review of required records and training documentation, operator understanding and competency, and the requirements of these rules.

641—46.5(136D) Construction and operation of tanning facilities. Unless otherwise ordered or approved by the department, each tanning facility shall be constructed, operated, and maintained to meet the following minimum requirements:

46.5(1) A tanning facility shall provide and post the following warning signs and statements that describe the hazards associated with the use of tanning devices:

a. A warning sign in a conspicuous location readily visible to persons entering the establishment. This warning sign shall use 0.5-inch (12.7-millimeter) letters for "DANGER, ULTRAVIOLET RADIATION" and 0.25-inch (6.4-millimeter) letters for all other lettering. The sign shall use red lettering against a white background, be at least 9.0 inches by 12.0 inches (22.9 centimeters × 30.5 centimeters) and have the following wording:

DANGER
ULTRAVIOLET RADIATION
— Overexposure can cause
• Eye and skin injury
• Allergic reaction
— Repeated exposure may cause
• Premature aging of the skin
• Skin cancer
— Failure to wear protective eyewear may result in
• Severe burns to eyes
• Long-term injury to eyes
— Medication or cosmetics may increase your sensitivity

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b. A warning sign with the identical wording set forth in 46.5(1)*"a"* posted within one meter of the tanning device in a conspicuous location readily visible to a person preparing to use the device. This warning sign shall use 0.5-inch (12.7-millimeter) letters for "DANGER, ULTRAVIOLET RADIATION" and 0.25-inch (6.4-millimeter) letters for all other lettering. The sign shall use red lettering against a white background and be at least 6 inches by 9 inches (15.2 centimeters × 22.9 centimeters) in size.

c. A tanning facility shall provide each consumer with a written warning statement prior to the consumer's initial exposure and annually thereafter which includes at least the following information:

(1) A representative list of potential photosensitizing drugs and agents. This list should at least include drugs or agents in the product classes of acne treatment, antibacterials, antibiotics, anticonvulsants, antidepressants, antidiabetics, antihypertensives, dye, estrogen and progesterones, melonogenics, perfumes and toilet articles, tranquilizers, antihistamines and antimicrobials/anti-infectious agents. A partial list of drugs and agents in these product classes is found in Appendices 1A, 1B, and 1C.

(2) Information regarding potential negative health effects related to ultraviolet exposure, including:

1. The increased risk of skin cancer later in life;
2. The increased risk of skin thickening and premature aging;
3. The possibility of burning or rashes, especially if using any of the potential photosensitizing drugs and agents. The consumer should consult a physician before using a tanning device if using medication, if there is a history of skin problems or if the consumer is especially sensitive to sunlight.

Appendix 2

SUN-REACTIVE SKIN TYPES USED IN CLINICAL PRACTICE

SKIN TYPE	SKIN REACTIONS TO SOLAR RADIATION [a]	EXAMPLES
I	Always burns easily and severely (painful burn). Tans little or none and peels.	[b] People most often with fair skin, blue eyes, freckles. Unexposed skin is white.
II	Usually burns easily and severely (painful burn). Tans minimally or lightly, also peels.	[b] People most often with fair skin; red or blonde hair; blue, hazel or even brown eyes. Unexposed skin is white.
III	Burns moderately and tans about average.	Normal average Caucasoid. Unexposed skin is white.
IV	Burns minimally, tans easily, and above average with each exposure. Exhibits IPD (immediate pigment darkening) reaction.	People with white or light brown skin, dark skin, dark brown hair, dark eyes (e.g., Mediterraneans, Orientals, Hispanics, etc.). Unexposed skin is white or light brown.
V	Rarely burns, tans easily and substantially. Always exhibits IPD reaction.	Brown-skinned persons (e.g., Amerindians, East Indians, Hispanics, etc.). Unexposed skin is brown.
VI	Never burns and tans profusely; exhibits IPD reaction.	Blacks (e.g., African and American Blacks, Australian and South Indian Aborigines); unexposed skin is black.

(a) Based in the first 45-60 minutes (=2-3 minimum erythema dose) exposure of the summer sun (early June) at sea level

(b) They may be of Celtic background (Irish or Scottish); others may even have dark hair or brown eyes

These rules are intended to implement Iowa Code chapters 136B, 136C, and 136D.

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NURSING BOARD[655]

[Prior to 8/26/87, see Nursing, Board of[590], renamed Nursing Board[655] under the "umbrella" of Public Health Department by 1986 Iowa Acts, ch 1245]

CHAPTER 5
CONTINUING EDUCATION

CHAPTER 6
NURSING PRACTICE FOR REGISTERED NURSES/LICENSED PRACTICAL NURSES

CHAPTER 7
ADVANCED REGISTERED NURSE PRACTITIONERS

CHAPTER 8
PETITIONS FOR RULE MAKING
(Uniform Rules)

CHAPTER 9
DECLARATORY ORDERS
(Uniform Rules)

CHAPTER 10
AGENCY PROCEDURE FOR RULE MAKING
(Uniform Rules)

CHAPTER 11
EXAMINATION OF PUBLIC RECORDS

CHAPTER 12
REGISTERED NURSE CERTIFYING ORGANIZATIONS/UTILIZATION AND COST CONTROL REVIEW

CHAPTER 13
DISCIPLINARY HEARING COSTS

CHAPTER 2
NURSING EDUCATION PROGRAMS
[Prior to 8/26/87, Nursing Board[590] Ch 2]

655—2.1(152) Definitions.

Approval. Recognition status given nursing education programs based on their compliance with the criteria specified in this chapter.

Clinical facilities. Those resources that provide experiences with or related to patients/clients for application and reinforcement of didactic content.

Clinical nurse preceptor. A registered nurse or licensed practical nurse practicing in a clinical setting who serves as a role model and clinical resource person for a specified period of time to an individual enrolled in an approved nursing education program.

Controlling institution. The institution which has authority and administrative accountability for the program(s).

Faculty. The teaching staff in nursing. This includes anyone who provides didactic or clinical instruction in nursing when the person is assigned by the program to provide this instruction for courses in the curriculum. The definition of faculty applies to any teaching staff in nursing regardless of the amount of time spent teaching, the level of payment, type of contract, or temporary nature of the position.

Head of the program. The dean, chairperson, director, or coordinator of the nursing education program(s) who is responsible for the administration of the program(s).

NCLEX. NCLEX means National Council Licensure Examination, the currently used examination.

Program. Course of study which leads to a nursing diploma, degree, or certificate. Multiple site programs offered by one controlling agency shall be considered as one program if the philosophy and curriculum are the same. Programs may include the following:

1. Practical nursing education. A vocational course of study which leads to a diploma in practical nursing and eligibility for the practical nurse examination, as described in 655—Chapter 3.
2. Basic nursing education. A course of study which leads to initial eligibility for the registered nurse licensing examination as described in 655—Chapter 3. These include:

Associate degree.

Diploma.

Baccalaureate degree.

3. Advanced formal education.

- Baccalaureate for registered nurses. A course of study designed for registered nurses which leads to a baccalaureate degree with a major in nursing.
- Formal advanced practice education program in nursing. A course of study in nursing which provides advanced knowledge and experiences which facilitate development of competencies in a specialized clinical area. This leads to eligibility for certification in the specialty and registration as an advanced registered nurse practitioner.
- Master's degree. A postbaccalaureate course of study which offers postgraduate study in nursing.
- Master's degree for registered nurses. A course of study designed for registered nurses which leads to a master's degree with a major in nursing.
- Doctorate degree. A postmaster's course of study which offers postgraduate study in nursing.

655—2.2(152) Approval of programs.

2.2(1) Approval status for each program shall be determined by the board. The board shall review all programs within a controlling institution at the same time, when feasible. A report shall be sent to the head(s) of the program(s) and controlling institution.

2.2(2) Interim approval shall be granted to a newly established program which meets the requirements of the board as specified in this subrule.

a. A controlling institution which proposes to establish or reopen a program shall:

(1) Submit a written statement of intent to the board at least nine months prior to expected opening date.

(2) Utilize an advisory committee composed of representatives from the community and nursing. Minutes of meetings shall be on file.

(3) Submit the following information to the board at least six months prior to expected opening date:

Program philosophy, objectives, and purpose which reflect the level of education to be taught.

Organizational chart.

A budget which demonstrates financial resources adequate for the planning, implementation, and continuation of the program.

Curriculum plan which demonstrates compliance with rule 2.5(152).

Availability of academic facilities adequate to meet program needs and learning needs of the student. See rule 2.4(152).

Availability of clinical facilities adequate to meet curriculum objectives.

Availability of qualified faculty as defined in rule 2.6(152).

Tentative time schedule for planning and initiation of the program.

b. The board may conduct a site visit to the controlling institution prior to acting upon interim approval. The submitted information will be discussed and the program's resources and clinical facilities visited.

c. The board shall review the statement of intent, submitted information, and written report of the site visit, if done, and take action. The board may seek further information, deny or grant interim approval to the program.

d. Faculty requirements.

(1) The faculty shall meet the qualifications outlined in subrule 2.6(2).

(2) The head of the program shall be employed for six months prior to the expected opening date.

(3) The other faculty of the program shall be employed prior to the beginning of teaching assignments. Sufficient time shall be allowed for orientation and preparation for teaching assignments.

e. Progress reports. The head of the program shall submit eight copies of the progress report three weeks prior to each regularly scheduled board meeting until full approval is granted by the board as defined in subrule 2.2(3).

f. Publicity. Publicity shall accurately reflect the approval status of the new program.

g. Interim approval shall continue until the board reviews the program following the graduation of the first class. Practical nursing or basic nursing programs shall be reviewed after results from the licensure examination of the first graduating class are available.

2.2(3) *Approval procedure.*

a. Site visits of the program. A representative of the board shall make a site visit to a program prior to the expiration of the approval status or if there is evidence that the program is no longer able to meet the criteria for approval.

(1) The purpose of the site visit is to examine educational objectives, review courses, programs, administrative practices, services, and facilities; and to determine if the program continues to meet the criteria for approval.

2.7(2) *School information.* Information about the program and the controlling institution shall be published at least every two years and shall include:

a. Philosophy and objectives of the program.
b. A general description of the program.
c. Curriculum plan.
d. Course descriptions.
e. Resources.
f. Faculty.
g. Tuition, fees, and refund policies.
h. Ethical practices, including recruitment and advertising.
i. Official dates.

2.7(3) *Program records.*

a. Records shall be dated and include:
(1) Course outlines.
(2) Minutes.
(3) Faculty personnel records.
(4) Correspondence.
(5) Reports.
(6) Catalogs and program bulletins.

b. If a program closes the board shall be informed about the location and maintenance of these records.

2.7(4) *Student records.*

a. Policies for records shall specify method for permanent protection and maintenance of individual records against loss, destruction, and unauthorized use.

b. The final record shall include the transcript and a summative performance statement.
(1) The final transcript includes:
1. Legal name of student.
2. Dates of admission, completion of the program, and graduation.
3. Courses which were accepted for transfer.
4. Signature of the proper program official.
5. Seal of the program or controlling institution or notarized signature of proper program official.
(2) The summative performance statement is a profile of the student at the time of graduation.

c. If a program closes, the board shall be informed about the location and maintenance of the student and graduate records.

655—2.8(152) Clinical facilities.

2.8(1) The clinical facilities shall provide adequate learning experiences to meet curriculum objectives.

2.8(2) The program shall inform the board of clinical facilities used for learning experiences.

a. The clinical facilities shall be accredited/approved by the appropriate agencies.
b. The board may conduct a site visit of the clinical facilities.
c. There shall be joint planning when more than one program uses the same facility for student experiences.

655—2.9(152) Preceptors.

2.9(1) Clinical nurse preceptors shall be selected by the nursing program in collaboration with a clinical facility to provide supportive clinical experiences consistent with curriculum objectives.

2.9(2) The qualifications of clinical nurse preceptors shall be appropriate to support the philosophy and goals of the nursing program.

a. The clinical nurse preceptor shall be employed by or maintain a current written agreement with the clinical facility in which a preceptored experience occurs.

b. The clinical nurse preceptor shall be currently licensed as a registered nurse/licensed practical nurse according to the laws of the state in which the preceptor practices.

c. The clinical nurse preceptor shall function according to written policies developed by the nursing education program for selection, evaluation, and reappointment. Written qualifications shall address educational preparation, experience, and clinical competence.

d. The program shall be responsible for informing the clinical nurse preceptor of the responsibilities of the preceptor, faculty, and students. The program shall retain ultimate responsibility for student learning and evaluation.

2.9(3) The program shall inform the board of clinical nurse preceptorship learning experiences.

a. Written preceptorship agreements shall be reviewed annually by the nursing program.

b. The board may conduct a site visit to clinical settings in which preceptorship experiences occur.

c. The rationale for the ratio of students to preceptors shall be documented by the program.

2.9(4) An individual who is not a nurse or a licensed practical nurse may serve as a preceptor when appropriate to the philosophy and goals of the nursing program.

655—2.10(152) Results of graduates who take the licensure examination for the first time. The program shall notify the board when the program or district national licensure examination passing percentage is lower than 95 percent of the national passing percentage for two consecutive calendar years. The NCLEX passing percentage shall be based on all first-time applicants for RN or LPN licensure in any jurisdiction who take the examination within six months of graduation. Upon notification by the program, the board shall implement the following process:

1. The program shall submit to the board within six months an institutional plan for assessment and improvement of NCLEX results, including outcomes and time lines. The plan shall address administration, faculty, students, curriculum, resources, policies and the nursing advisory committee.

2. The program shall submit annual progress reports to the board while the NCLEX passing percentage remains below 95 percent of the national passing percentage.

3. The board may initiate provisional program approval as specified in subrule 2.2(3) if the program or district NCLEX average does not equal or exceed 95 percent of the national passing percentage within two calendar years.

655—2.11(152) Reports to the board.

2.11(1) *Annual reports.* The head of the nursing program shall submit an annual report to the board on forms provided and shall include:

a. Progress toward achievement of stated program goals of the past academic year.

b. Qualifications and major responsibilities of the head of the program and each faculty member.

c. Policies for admission, progression, and graduation of students.

d. Policies for student health and welfare.

e. Current enrollment by class.

f. Number of admissions and graduations per year for past five years.

g. Passing percentages of graduates on licensure examinations for past five years.

h. Employment data for graduates.

i. Curriculum plan.

j. Descriptions of resources, clinical facilities, preceptorship experiences, and contractual arrangements.

k. Copy of audited fiscal reports, including a statement of income and expenditures.

l. Goals for present academic year.

m. Program catalog.

2.11(2) *Special reports.* The program shall notify the board of the following:

a. Change of controlling institution. Information shall include official names of the programs and controlling institution, organizational chart of the controlling institution, and names of administrative officials.

b. Changes in administrative personnel in the program or the controlling institution.

c. Opening of a new site or campus.

2.11(3) *Changes requiring board approval.*

a. These changes require the submission of eight copies of the proposed change at least three weeks prior to the next regularly scheduled board meeting and include but need not be limited to the following:

(1) Changes in the curriculum which lengthen or shorten the program.

(2) Addition or deletion of clinical or didactic credit hours in a course.

(3) Changes in course requirements for graduation.

b. Changes requiring the submission of one copy of the proposed change. A board representative shall review the proposed change for approval. If the change is not approved, seven additional copies shall be requested and the matter shall be submitted for board approval. These changes include but need not be limited to the following:

(1) Changes in the philosophy, objectives, or organizing framework used to define the curriculum.

(2) Change in the predominant method of instruction (e.g., where a course taught by faculty is shifted to computer, programmed self-study, or correspondence).

(3) Rearrangement of the sequence of required courses.

These rules are intended to implement Iowa Code section 152.5.

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CHAPTER 431
VEHICLE RECYCLERS

CHAPTERS 432 to 449
Reserved

CHAPTER 450
MOTOR VEHICLE EQUIPMENT

CHAPTER 451
EMERGENCY VEHICLE PERMITS

CHAPTER 452
REFLECTIVE DEVICES ON SLOW-MOVING VEHICLES

CHAPTER 453
WEIGHT EQUALIZING HITCH AND SWAY CONTROL DEVICES FOR TRAILERS

CHAPTER 454
TOWING WRECKED OR DISABLED VEHICLES

CHAPTERS 455 to 479
Reserved

CHAPTER 480
ABANDONED VEHICLES

CHAPTERS 481 to 499
Reserved

MOTOR CARRIERS

CHAPTER 500
INTERSTATE REGISTRATION AND OPERATION OF VEHICLES

CHAPTERS 501 to 504
Reserved

CHAPTER 505
INTERSTATE MOTOR VEHICLE FUEL PERMITS

505.1(452A) Definitions
505.2(452A) General information
505.3(452A) General stipulations
505.4(452A) Quarterly reports
505.5(452A) Audits—required records
505.6(452A) Hearings

CHAPTERS 506 to 510
Reserved

CHAPTER 511
SPECIAL PERMITS FOR OPERATION AND MOVEMENT OF VEHICLES AND LOADS OF EXCESS SIZE AND WEIGHT

511.1(321E) Definitions
511.2(321E) Location and general information
511.3(321E) Movement under permit
511.4(321E) Permits
511.5(321E) Fees and charges
511.6(321E) Insurance and bonds
511.7(321,321E) Issuance of annual permits
511.8(321,321E) Issuance of all-system permits
511.9(321,321E) Multitrip permits
511.10(321,321E) Issuance of single-trip permits
511.11(321,321E) Maximum axle weights and maximum gross weights for vehicles and loads moved under permit
511.12(321,321E) Movement of vehicles with divisible loads exceeding statutory size or weight limits
511.13(321E) Towing units
511.14 Reserved
511.15(321E) Escorting
511.16(321,321E) Permit violations

CHAPTER 512
Reserved

CHAPTER 513
COMPACTED RUBBISH VEHICLE PERMITS

513.1(321) Definitions
513.2(321) General stipulations
513.3(321) Application
513.4(321) Replacement permit
513.5(321) Permit violations

CHAPTERS 514 to 519
Reserved

CHAPTER 520
REGULATIONS APPLICABLE TO CARRIERS

520.1(321) Safety and hazardous materials regulations
520.2(321) Definitions
520.3(321) Motor carrier safety regulations exemptions
520.4(321) Hazardous materials exemptions
520.5 Reserved
520.6(307,321) Out-of-service order
520.7(321) Driver's statement

CHAPTERS 521 to 523
Reserved

CHAPTER 452
REFLECTIVE DEVICES ON SLOW-MOVING VEHICLES

[Appeared as Ch 3, Department of Public Safety, 1973 IDR]
[Prior to 6/3/87, Transportation Department[820]—(07,E) Ch 3]

761—452.1(321) Slow-moving vehicle. Rescinded IAB 4/5/00, effective 5/10/00.

761—452.2(321) Required equipment. Rescinded IAB 4/5/00, effective 5/10/00.

761—452.3(321) Alternative reflective device. If a person operating a vehicle drawn by a horse or mule objects for religious reasons to using a reflective device that complies with the standards of the American Society of Agricultural Engineers, the vehicle may be identified by an alternative reflective device that is in compliance with the following:

452.3(1) The alternative reflective device shall consist of one-inch-wide strips applied to the rear of the vehicle. The combined length of the strips shall be at least 72 inches. The strips, when applied, shall approximate the outline of the vehicle.

452.3(2) The reflective material may be black, gray, silver or white in color, but must reflect white when illuminated by other vehicles' headlamps.

452.3(3) The reflective material shall be visible from a distance of not less than 500 feet from the rear of the vehicle when illuminated by other vehicles' headlamps.

452.3(4) The reflective material shall be kept free of dirt and debris.

This rule is intended to implement Iowa Code Supplement section 321.383(2).

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CHAPTER 2
MISSION AND STRUCTURE

877—2.1(84A) Mission. The division of workforce development center administration was established by the director as authorized under Iowa Code section 84A.1(3). The mission of the division is to develop and administer employment, placement, and training services in all 99 counties of Iowa.

877—2.2(84A) Overall organization.

2.2(1) *Organization.* The division of workforce development center administration is under the direction of the division administrator and divided into three bureaus: administrative service bureau, service delivery bureau, and the enterprise development, implementation and evaluation bureau.

2.2(2) *Administrative service bureau.* The administrative service bureau is under the direction of a bureau chief who assists the division administrator in planning, directing and coordinating activities for the division. The chief directs the administrative support functions of the bureau. The bureau is responsible for the administration of the following programs: work opportunity tax credit, alien labor certification, child labor, testing, bonding certification, and the migrant seasonal farm worker program, as well as other duties assigned by the division administrator.

2.2(3) *Service delivery bureau.* The service delivery bureau is under the direction of a bureau chief who assists the division administrator in planning, directing and coordinating activities for the division. The chief directs the monitoring and technical assistance functions of the bureau. The bureau is responsible for the administration of the following programs: Iowa conservation corps, Job Training Partnership Act, state labor management cooperation, mentor advisory board, nontraditional employment, workforce investment, quality jobs, PROMISE JOBS, dislocated workers, and rapid response, as well as other duties assigned by the division administrator.

2.2(4) *Enterprise development, implementation, and evaluation bureau.* The enterprise development, implementation and evaluation bureau is under the direction of a bureau chief who assists the division administrator in planning, directing and coordinating activities for the division. The chief directs the administrative support and technical functions of the bureau. The bureau is responsible for the administration of the consolidation of the employment and training services delivered through a competitive regional service delivery model in consultation with the regional advisory board, as well as other duties assigned by the division administrator.

877—2.3(17A,84A) Criticism of agency rule. The division administrator of the Division of Workforce Development Center Administration, Workforce Development Department, 150 Des Moines Street, Des Moines, Iowa 50309, is designated as the office where interested persons may submit by mail criticism regarding an administrative rule of the workforce development board/services division. A criticism of a specific rule must be more than a mere lack of understanding of a rule or a dislike regarding the rule. To constitute a criticism of a rule, the criticism must be in writing, indicate it is a criticism of a specific rule, be signed by the complainant, not be part of any other filing with the department of workforce development, and have a valid or legal basis for support. All requests for criticism received on any rule will be kept in a separate record for a period of five years by the division of workforce development center administration and be a public record open for public inspection. All requests for criticism must be in the following format:

DEPARTMENT OF WORKFORCE DEVELOPMENT
DIVISION OF WORKFORCE DEVELOPMENT CENTER ADMINISTRATION

(NAME OF PERSON SUBMITTING CRITICISM). } CRITICISM OF (SPECIFY RULE THAT IS UNDER CRITICISM).

Reasons for criticism:
Name, address, telephone number and signature of person submitting the criticism.

The administrative rules committee of the workforce development board will periodically review criticisms received for potential rule changes.

This rule is intended to implement Iowa Code chapter 17A as amended by 1998 Iowa Acts, chapter 1202, and chapter 84A.

***877—2.4(17A,ExecOrd11) Requests for waiver of rules.** Requests for waiver of a rule in the Workforce Development Board/Services Division[877] of the Iowa Administrative Code shall be made to the Division Administrator, Division of Workforce Development Center Administration, 150 Des Moines Street, Des Moines, Iowa 50309.

2.4(1) Waivers from division rules shall not be granted unless the following circumstances are met:

a. The department has exclusive rule-making authority to promulgate the rule from which waiver is requested; and

b. No statute or rule otherwise controls the grant of a waiver from the rule from which waiver is requested.

2.4(2) The person that requests waiver of the rule must provide clear and convincing evidence that:

a. Compliance with the rule will create an undue hardship on the person requesting the waiver.

b. Substantially equal protection of health and safety will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.

c. The waiver will not harm other persons and will not adversely affect the public interest.

2.4(3) The director shall grant or deny the waiver within 60 days of the date the request is filed with the department after review and recommendation of the division administrator. A denial of a request for a waiver is absolutely final and is not appealable. The director shall deny the request for waiver of a state or federal statute. If the request for waiver relates to a time requirement of a rule, the request must be received before the time specified in the rule has expired. The director may deny the request if the request does not comply with the provisions of this rule.

2.4(4) Waivers are granted at the complete discretion of the director after consideration of all relevant factors including, but not limited to, the following:

a. The need of the person or entity directly affected by the exception. Exceptions will be granted only in cases of extreme need.

b. Whether there are exceptional circumstances justifying an exception to the general rule applicable in otherwise similar circumstances.

c. Whether granting the exception would result in a net savings to the state or promote efficiency in the administration of programs or service delivery. Net savings or efficiency will make an exception more likely.

d. In the case of services, assistance, or grants, whether other possible sources have been exhausted. Exceptions will not generally be granted if other sources are available.

e. The cost of the exception to the state and availability of funds in the department's budget.

*Effective date of March 15, 2000, delayed 70 days by the Administrative Rules Review Committee at its meeting held March 10, 2000.

2.4(5) All requests for waiver must substantially conform to the following form:

(NAME OF PERSON REQUESTING WAIVER). } REQUEST FOR WAIVER OF (SPECIFY RULE FOR WHICH WAIVER IS REQUESTED).

Reasons for requesting waiver:

Name, address, telephone number and signature of person submitting waiver request.

The specific rule to which an exception is requested or the substance thereof.

The specific waiver requested.

The nature of the waiver requested, including any alternative means or other proposed condition or modification proposed to achieve the purpose of the rule.

2.4(6) The director may condition the grant of a waiver on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

2.4(7) A waiver is void if the material facts upon which the request is based are not true or if material facts have been withheld. The director may, at any time, cancel a waiver upon appropriate notice if the director finds the facts as stated in the request appear not true, material facts have been withheld, the alternative means of compliance provided in the waiver has failed to achieve the objectives of the statute, or the person requesting the waiver has failed to comply with conditions set forth in the waiver approval.

2.4(8) All grants of waivers shall be indexed and available to members of the public in the Division of Workforce Development Center Administration, 150 Des Moines Street, Des Moines, Iowa 50309. In addition, the director shall notify the workforce development board of any ruling to grant a waiver at its next regularly scheduled meeting following the ruling.

This rule is intended to implement Iowa Code chapter 17A and Executive Order Number Eleven.

These rules are intended to implement Iowa Code chapter 17A as amended by 1998 Iowa Acts, chapter 1202, Iowa Code section 84A.1 and Iowa Code chapter 96.

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CHAPTER 3
Reserved

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DAIRIES

DAIRIES (cont'd)

Transportation **21**—68.2(6), 68.71; **761**—400.47, *see also Milk/Dairy Products subheads Bulk Tankers above; Haulers above*
Violations/penalties **21**—68.21, 68.36, 68.68
Water supply **21**—68.27, 68.35

DAMS
See also FLOOD CONTROL
Construction/operation
Abandonment, removal **567**—73.10, 73.11
Animal feeding operations, distance **567**—72.2(9), 72.3(5)
Approval **567**—71.3, 72.3(2)*c*
Movable structures **567**—73.1
Permits **567**—52.20
Taxation **701**—19.10(2)*e*
Definitions **567**—70.2
Hazards **567**—72.3(2), 73.30–73.32
Inspections **567**—73.20–73.26, 73.30–73.32
Water levels **567**—73.2

DATA PROCESSING
See COMPUTERS

DAY CARE
Adult **321**—ch 24; **441**—77.30(3), 77.30(5)*g*, 77.33(6)*f*, 77.34(5)*g*, 77.34(7), 77.37(15)*f*, 77.39(20), 78.34(3), 78.34(5)*c*, 78.37(1), 78.38(5)*c*, 78.38(7), 79.1(2), 83.2(1)*g*, 83.6, 83.26, 150.3(5)*p*(2), 150.22(7)*p*, 153.35, ch 171, 176.6(7), *see also HUMAN SERVICES DEPARTMENT: Medical Assistance (Medicaid): Day Services, Adult*
Children, *see CHILDREN: Care Services*

DEAF
See also DEAF SERVICES DIVISION; SPEECH PATHOLOGY AND AUDIOLOGY
Hearing aid, medical assistance **441**—77.13, 78.14, 78.28(4), 79.1(2), 80.2(2)*b*
School, state
Generally **681**—ch 16
Address **681**—16.1(4)
Administrators, financial disclosure **351**—11.2"32" ap–ar
Forms **681**—16.6
Organization **681**—11.1(7,8), 16.1

DEAF SERVICES DIVISION (cont'd)
Services

Library **429**—2.3(7), 4.1(9,10)
Telecommunications devices for deaf (TDD) **429**—4.1(12,13)
Telephone Pioneers of America (TPA) **429**—4.1(12)

DEATH
See also LIVESTOCK
Abuse, domestic, review team **641**—ch 91
Autopsies
Certificates, death **641**—101.1, 102.1(2), *see also Certificates below*
Definition **645**—100.1
Fees **641**—126.3
Sudden infant death syndrome (SIDS) **641**—126.1
Beneficiaries
Credit union accounts **189**—8.5
IPERS benefits **581**—21.10(1,7,8,13,14,16,17), 21.11(7), 21.14(3,4), 21.18(3), 21.19(2)*a*, 21.27, 21.29(3)*b,c,g*
Burial, *see BURIAL*
Certificates **481**—51.12(2)*b*, 57.16(1)*s*, 58.15(2)*j*, 62.18(1)*p*, 63.17(1)*s*; **641**—96.1, 98.2, 99.12, 101.1(2,3), 101.2, 101.3, 101.5(4), 101.8, 102.1(2), 104.1, 104.2, 127.2
Children, review team **641**—ch 90
Crime victims, medical examiner investigations **641**—127.1(1,7)
Disease, *see DISEASES: Communicable*
Disinterment **641**—101.7; **645**—100.1, 100.8
Employment benefits **871**—25.14
Family investment program (FIP) recipients **441**—45.25, 56.2
Fetus **641**—101.4–101.6, 102.1(2); **645**—100.2, 100.3, 100.11
Fire-related, investigations **661**—5.6
Foster care facilities **441**—114.21
Funerals, *see FUNERALS*
Health care facilities, *see HEALTH CARE FACILITIES: Residents*
Hospices **481**—53.19
Hospitals, *see HOSPITALS*
Insurance, benefits, *see INSURANCE subheads Accident/Health: Individual Policies; Life*
Investigations, *see Medical Examiner's Duties below*
Loans, records **187**—15.3(2)*c*
Lottery prizes **705**—1.22
Maternal **641**—ch 5

*Rules **645**—chs 6–17 apply to all professional licensure boards

DISASTERS (cont'd)

Taxation, corporate, operating loss **701**—53.2(3)*c*
Telephone, enhanced 911 service **199**—39.2(1)*e*, 39.2(2); **605**—ch 10; **701**—40.39; **721**—21.810
Volunteers, employee leave **581**—14.14; **681**—3.151
Water usage, restriction **567**—52.10

DISCLOSURE
Banks **187**—9.2(7); **191**—50.81(4–6), 50.83; **781**—ch 5, *see also Mortgage Loans below*
Bonding activities, obligations **781**—7.3
Campground membership advertisements **61**—25.5
Credit **781**—ch 5
Credit unions **189**—18.3; **191**—50.83(2–4)
Elections, campaign disclosure, *see ETHICS AND CAMPAIGN DISCLOSURE*
Employees **361**—ch 9; **581**—18.5
Environmental audits **567**—ch 12
Executive branch officials **361**—ch 9
Funeral directors, costs **645**—101.212(13)
Gaming establishments **491**—22.13(9,10)
Grain dealers **21**—91.8
Health care facilities **441**—81.13(19)*p*, 82.2(1)*e*
HIV test results, sexual assault **641**—11.74
Industrial loan corporations **781**—ch 5
Insurance
  Accident/health **191**—28.3, 28.14, 36.7, 37.1, 37.15, 39.7, 39.10(4), 41.21
  Auto **191**—15.10
  Life
    Advertising/sales **191**—15.3(10), 15.4, 15.8, ch 15 Appendix I
    Annuities **191**—15.3(10), 16.10 "Exhibit B"
    Credit **191**—28.3, 28.14
  Long-term care **191**—39.7(5), 39.20"4," 72.5
  Mortgage loans **191**—5.50–5.55
  Service contracts/records **191**—23.23, 54.13(4)*d*
Labor organizations, racetrack employees **491**—13.14(4,5,7)
Lobbyists, reports **351**—13.2
Mortgage loans **189**—9.2(9); **191**—5.50–5.55; **197**—ch 5, 11.6, 12.4