

PUBLIC HEALTH DEPARTMENT [641]
Adopted and filed

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials"; Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials"; Chapter 40, "Standards for Protection Against Radiation"; Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"; Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists"; and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations"; Iowa Administrative Code.

The following itemize the adopted changes.

Items 1, 2, 6, 8, 9 to 18, 22 to 25, 28, 29, 31, 33 to 35, 37 to 47, 51 to 53, 56 to 58, and 81 to 92 amend the rules to reflect current federal regulations, NRC compatibility requirements and federal X-ray standards.

Items 3, 19, 21, 48, 50 correct terminology, wording, and references.

Items 4 and 49 delete wording regarding effective dates since the effective dates have passed.

Item 5 adds wording to clarify who is a shipper of radioactive waste.

Item 7 adds wording to allow the agency to revoke a registration for facilities who provide X-ray services.

Item 20 adds requirements for posting or labeling because of enforcement problems.

Items 26, 30, 32, and 71 add a definition rescinded from Chapter 38 and change and add wording to reflect concerns of the Board of Medical Examiners and the agency legal staff regarding healing arts screening.

Item 27 clarifies the responsibilities in the use of X-ray equipment.

Item 36 adds new language for retention of X-ray films by facilities.

Items 54 and 55 move posting and training requirements for operators to one subrule.

Items 59 to 70 add or correct wording to reflect FDA compatibility for mammography.

Items 72 to 80 reflect changes in testing for all individuals certified under Chapter 42 and training for limited diagnostic radiographers. These changes were in response to concerns raised by educators and agency staff and to resolve enforcement issues.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on December 10, 2002, as **ARC 2272B**. A public hearing was held on February 25, 2003. No person attended the hearing. Nine sets of written comments were received, reviewed, and incorporated as appropriate. The changes made from the Notice of Intended Action are listed below.

1. In Item 2, the amendment to the definition of "person" was not adopted based on the NRC's recommendations.

2. In Item 4, in 38.8(6)"b"(3), the word "facility" was changed to "organization." "Facilities" are not allowed to offer testing. The subparagraph now reads as follows: "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 160, depending upon the testing organization chosen.

3. In Item 12, 39.4(29)"j"(2)"2," the third bulleted paragraph, the reference was changed from "39.4(29)"j"(2)"4" to "39.4(29)"j"(2)"2." The third bulleted paragraph now reads as follows: " This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)"j"(2)"2."

4. In Item 13, 39.4(29)"j"(2)"5," the reference was changed from 39.4(20)"j"(2)"2" to 39.4(29)"j"(2)"2." The numbered paragraph "2" now reads as follows: " Shall provide to the agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the NRC, or agreement state license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)"j"(2)"2," first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist."

5. Item 15 of the noticed document was not adopted. The changes were submitted in error. Items 16 through 93 of the Notice were renumbered as Items 15 through 92.

6. In Item 15, in 39.4(29)"i"(3), the phrase "issued by an agreement state," was changed to " issued by the NRC or an agreement state." This allows recognition of NRC issued licenses in Iowa. The subparagraph (3) now reads as follows: " The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device to persons licensed to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, and to persons who hold an equivalent license issued by the NRC or an agreement state;"

7. In Item 24, in 641—Chapter 40, Appendix A, superscript paragraph ^c, the parenthetical phrase "(e.g., radiodine)" was corrected to read "(e.g., radioiodine)." Superscript paragraph ^c now reads as follows: "^c The licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine)."

8. In Item 27, in 41.1(3)"a"(3)"1," the following phrase was added "unless automatically set by the X-ray system.) This phrase allows the use of new technology that automatically senses the patient's size and sets the equipment accordingly. The numbered paragraph "1" now reads as follows: " Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;"

9. In Item 28, in 41.1(3)"a"(5)"2," the phrase "direct scatter radiation" was corrected to read "scattered primary radiation." The numbered paragraph "2" now reads as follows: "The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent."

10. In Item 29, in 41.1(3)"a"(7), the proposed phrase "the individual has been physically examined by" was changed to "there is a previously established professional relationship with the." The phrase "which includes a physical examination unless it is otherwise clinically appropriate" was added after "Iowa code chapter 152." The proposed phrase "and (2) the individual has received a written order for the radiation exposure authorized by such practitioner" was changed to "and (2) a written order for the radiation exposure has been issued by the individual in (1)." The phrase "The written order may be issued after an exposure that is the result of an emergency or surgery setting" was added to (2). These changes were made after

consulting with the Board of Medical Examiners, the Iowa Hospital Association, the Iowa Medical Society, and the Iowa Osteopathic Society. The paragraph now reads as follows: "Individuals shall not be exposed to the useful beam unless (1) there is a previously established professional relationship with the 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, which includes a physical examination unless it is otherwise clinically appropriate; and (2) a written order for the radiation exposure has been issued by the individual in (1). The written order may be issued after the exposure that is the result of an emergency or surgery setting. This provision specifically prohibits deliberate exposure for the following purposes:"

11. In Item 33, in 41.1(3)"f"(1)"2," the word "developed" was changed to "processed" so that it includes all parts of the processing procedure. The phrase "The specified developer temperature and immersion time shall be posted in the darkroom" was added. This subparagraph addresses manual processing and the posting reminds the operator of the correct procedures. The numbered paragraph "2" now reads as follows: "Film shall be processed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom."

12. In Item 34, in 41.1(3)"f"(2)"1," the word "developed" was changed to "processed" so that it includes all parts of the processing procedure. The phrase "The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor" was not adopted. This phrase is not necessary for automatic processors. The numbered paragraph "1" now reads as follows: " Films shall be processed in accordance with the time-temperature relationships recommended by the film manufacturer."

13. In Item 35, in 41.1(3)"g," in subparagraph (1), the word "recommended" was not adopted. Subparagraph (1) now reads as follows: "If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period." In subparagraph (6) the word "medical" was changed to "film." The phrase "the records must be sent" was changed to "the film records must be sent." This subrule addresses film records not medical records. Subparagraph (6) now reads as follows: " A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal."

14. In Item 45, in 41.1(6)"g"(2), the phrase " $C \text{ kg}^{-1} \text{ mAs}^{-1}$ (or mR/mAs)" was changed to " $\text{mR/mAs} (C \text{ kg}^{-1} \text{ mAs}^{-1})$." This change is to make the rules uniform. Subparagraph (2) now reads as follows: "Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $\text{mR/mAs} (C \text{ kg}^{-1} \text{ mAs}^{-1})$, obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_x \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection."

15. In Item 54, in 41.2(14)"f"(2), the introductory paragraph, the phrase "a feeding individual" was changed to "a breast-feeding individual." This identifies the proper individual.

Subparagraph (2), the introductory paragraph, now reads as follows: "A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a breast-feeding individual that:" In subparagraph (4), the phrase "to the agency 15 days" was changed to read "to the agency within 15 days." This change is for clarity. Subparagraph (4), the introductory paragraph, now reads as follows: "The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)"f"(1) or (2)."

16. In Item 68, in 41.7(5)"c"(3), the phrase "technologist only performs" was changed to read "technologist performs only." The phrase "technologist will perform" was changed to "technologist must perform." These changes were for clarity. The reference "41.6(3)"b"" was corrected to read "41.6(3)"b"(4)"1."" Subparagraph (3) now reads as follows: "If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures 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 between the two. The requirements of 41.6(3)"b"(4)"1" do not apply in this case."

17. In Item 70, in 641—chapter 41, Appendix C, an additional numbered paragraph "18" was added as follows: "18. A copy of IRB for a research project or information justifying the research project." This was a recommendation from the public comments.

18. In Item 71, in 42.1(2), in the definition of "diagnostic radiographer," the phrase "dental radiographer" was stricken and replaced with "podiatric or dental assistant with radiography qualification." This was the recommendation of the Board of Dental Examiners. The Iowa Code Chapter "512" was corrected to "152." In numbered paragraph "2" the phrase "restricted to that area" was changed to "restricted to performing radiography in that area." This change is for clarity. Numbered paragraph "2" now reads as follows: "Limited diagnostic radiographer" applies X-radiation to not more than three of the following body parts: chest, extremities (upper and lower), spine, or sinus. This individual is restricted to performing radiography in that area of the facility specifically designed for X-ray. This individual may not perform pediatric radiography (children under three years of age) without additional training in pediatric radiography taken as a part of the basic limited training or a specifically approved training program (see 42.2(6))."

19. In Item 75, in 42.2(7), the phrases "nuclear technologist" were corrected to "nuclear medicine technologist." The subrule now reads as follows: "Requirements for operators of dual imaging devices. When a unit is operated as a nuclear medicine imaging device, the operator must have a permit to practice as a nuclear medicine technologist and meet the requirements of 641—42.4(136C). When the unit is operated as a radiologic technology imaging device, the operator must have a permit to practice as a general diagnostic radiographer and meet the requirements of 641—42.3(136C). When a unit is operated in dual mode, the operator must have a permit to practice as a nuclear medicine technologist."

20. Item 76, in 42.2(8), the phrase "within six months of the date of the initial certification" was added to the first sentence. The second sentence "A temporary permit will be issued for six months until the examination is passed" was stricken. The phrase "temporary permit" was changed to "temporary 6 month permit." The word "direct" was stricken from "direct supervision." The phrase "with the permit in the same category" was changed to "with the permit in the same or higher category." The last sentence of the noticed item was stricken. The subrule now reads as follows: "Examinations. All individuals seeking certification under

641—Chapter 42 must pass a written examination within six months of the date of the initial certification. The temporary six month permit will be issued to allow the individual to practice under supervision of a licensed practitioner, an authorized user listed on a radioactive materials license, or a permitted individual with the permit in the same or higher category. The individual will be issued an annual permit upon passing the examination."

The State Board of Health adopted these amendments on March 12, 2003.

These amendments will become effective May 7, 2003.

These amendments are intended to implement Iowa Code chapter 136C.

The following amendments are adopted.

ITEM 1. Amend subrule **38.1(2)** as follows:

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January~~ May 1, 2003.

ITEM 2. Amend rule **641—38.2(136C)** as follows:

Rescind the definitions of "healing arts screening" and "recordable event."

Amend the following definitions:

"Beam axis" means ~~the axis of rotation of the beam limiting device~~ a line from the source through the centers of the X-ray fields.

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

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. See 641—subrule 42.1(2) for definitions of "lower extremities" and "upper extremities" for purposes of certification standards.

"Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"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)~~ 0.1 rem (1 mSv) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

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

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or

radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material 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~~ In accordance with the directions of the authorized user for procedures performed in 641—subrules 41.2(31) and 41.2(33).

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

- a. and b. No change.
- c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

d. No change.

ITEM 3. Amend subrule **38.8(1)**, paragraph "e," as follows:

e. All mammography facilities providing services in Iowa must submit a \$50 annual ~~accreditation~~ authorization certification fee.

ITEM 4. Amend subrule **38.8(6)**, paragraph "b," as follows:

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~~ 80 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~~ 85 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~~ 160, depending upon the testing facility testing organization chosen, ~~effective January 1, 2000.~~

ITEM 5. Amend subrule **38.8(11)**, paragraph "a," subparagraph (3), as follows:

(3) \$50 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low-level radioactive waste or shipped to a storage site to be held for future disposal.

ITEM 6. Amend subrule **39.1(3)** as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January~~ May 1, 2003.

ITEM 7. Amend subrule **39.3(3)** by adopting **new** paragraph "f" as follows:

f. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapters 38 through 45.

ITEM 8. Amend subrule **39.4(22)**, paragraph "d," subparagraph (3), numbered paragraph "13," first bulleted paragraph, as follows:

- Shall register devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, .01 mCi (.37 MBq) of radium-226, or 1 mCi (37 MBq) of any other transuranic (i.e., element with atomic number greater than uranium (92)), or 1000 times the activity indicated in Appendix B of 641—Chapter 39 (excluding hydrogen-3), based on the activity indicated on the label. Each address for a location of use, as described in 39.4(22)"d"(3)"13," represents a separate general licensee and requires a separate registration and fee;

ITEM 9. Amend subrule **39.4(22)**, paragraph "d," by adopting **new** subparagraph (5) as follows:

(5) A general license to install devices generally licensed in 39.4(22)"d." Any person who holds a specific license issued by an agreement state authorizing the holder to manufacture, install, or service a device described in 39.4(22)"d" within such agreement state is hereby granted a general license to install and service such device in any non-agreement state and a general license to install and service such device in offshore waters, as defined in 641—45.1(136C), provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with the applicable provision of the specific license issued to such person by the agreement state, and

2. Such person assures that any labels required to be affixed to the device under regulations of the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

ITEM 10. Amend subrule **39.4(29)**, paragraph "j," subparagraph (1), numbered "2," paragraph, by adopting the following **new** bulleted paragraph:

- Operating as a nuclear pharmacy within a federal medical institution.

ITEM 11. Amend subrule **39.4(29)**, paragraph "j," subparagraph (1), numbered paragraph "3," as follows:

3. The applicant submits ~~the following information on the radionuclide~~; the chemical and physical form of the radionuclide; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

ITEM 12. Amend subrule **39.4(29)**, paragraph "j," subparagraph (2), numbered paragraph "2", as follows:

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- ~~the~~ This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),
- This individual meets the requirements specified in 641—subrules 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)"j"(2)"2."

ITEM 13. Amend subrule **39.4(29)**, paragraph "j," subparagraph (2), by adopting **new** numbered paragraphs "4" and "5" as follows:

4. Shall permit the actions authorized in 39.4(29)"j"(2)"1" and "2" that are permitted in spite of more restrictive language in license conditions.

5. Shall provide to the agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the NRC, or agreement state license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)"j"(2)"2," first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist.

ITEM 14. Amend subrule **39.4(29)**, paragraph "j," subparagraph (3), introductory paragraph, as follows:

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation ~~to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation.~~ The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

ITEM 15. Amend subrule **39.4(29)**, paragraph "i," subparagraph (3), as follows:

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device is licensed by the agency for distribution to persons licensed pursuant to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, or under and to persons who hold an equivalent license licenses of the U.S. Nuclear Regulatory Commission, issued by the NRC or an agreement state, or a licensing state, provided that such labeling for sources which do not require long-term storage may be on a leaflet or brochure which accompanies the source;

ITEM 16. Amend subrule **39.4(31)** by adopting **new** paragraph "c" as follows:

c. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of 641—subrule 45.1(10).

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(4) The applicant submits written operating and emergency procedures as described in 641—subrule 45.2(4).

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed six months as described in 641—subrule 45.1(11).

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (641—paragraph 45.1(10)"d") and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe the methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 641—subrule 45.1(5).

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by 641—Chapters 38, 39, 40, and 45 will be located.

ITEM 17. Amend subrule **40.1(5)** as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before ~~January~~ May 1, 2003.

ITEM 18. Amend subrule **40.32(1)**, paragraph "a," as follows:

a. Each sealed source, except as specified in ~~40.34(2)~~ 40.32(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

ITEM 19. Amend rule **641—40.60(136C)** by adopting the following **new** subrule:

40.60(4) Deceptive posting or labeling. The licensee or registrant shall ensure that adequate measures are taken to prevent deceptive posting or labeling.

ITEM 20. Amend subrule **40.65(4)**, paragraph "a," as follows:

a. Removable radioactive surface contamination exceeds the limits of ~~641—paragraph 39.5(15)"h"~~ 49 CFR 173.443; or

ITEM 21. Amend rule **641—40.80(136C)** by adopting the following **new** subrule:

40.80(5) Notwithstanding the requirements of 40.80(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

ITEM 22. Amend subrule **40.97(1)**, paragraph "b," by rescinding subparagraph (3) and renumbering subparagraphs (4) to (6) as (3) to (5).

ITEM 23. Rescind rule **641—Chapter 40, Appendix A**, and adopt the following **new** Appendix A in lieu thereof:

APPENDIX A
PROTECTION FACTORS FOR RESPIRATORS^a

	Operating Mode	Assigned Protection Factor

I. Air-Purifying Respirators (particulate 1A ^b only) 1A ^c :		
Filtering facepiece disposable ^d	Negative Pressure	(^d)
Facepiece, half ^e	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere-Supplying Respirators (particulate, gases and vapors)(1A ^f):		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	(^g)
2. Self-contained breathing apparatus (SCBA):		
Facepiece, full	Demand	^h 100
Facepiece, full	Pressure Demand	^h 10,000
Facepiece, full	Demand, Recirculating	^h 100
Facepiece, full	Positive Pressure Recirculating	^h 10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above	

^a These assigned protection factors apply only in a respiratory protection program that meets the requirement of 641—Chapter 40. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table I, Column 3, of Appendix B to 641—Chapter 40 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

^b Air-purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air-purifying respirators with APF=100 must be equipped with

particulate filters that are at least 99 percent efficient. Air-purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

^c The licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

^d Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 641—40.50(136C) apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

^e Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient, and all other requirements of 641—Chapter 40 are met.

^f The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

^g No NIOSH approval schedule is currently available for atmosphere-supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met.

^h The licensee should implement institutional controls to ensure that these devices are not used in areas immediately dangerous to life or health.

ⁱ This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

ITEM 24. Amend subrule **41.1(1)** as follows:

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.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 2002~~ May 1, 2003.

ITEM 25. Amend subrule **41.1(2)** by adopting the following **new** definition in alphabetical order:

"Healing arts screening" means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)"a"(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

ITEM 26. Amend subrule **41.1(3)**, paragraph "a," introductory paragraph, as follows:

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum test performed by a registered service facility according to the following schedule:

ITEM 27. Amend subrule **41.1(3)**, paragraph "a," subparagraph (3), numbered paragraph "1," as follows:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

ITEM 28. Amend subrule **41.1(3)**, paragraph "a," subparagraph (5), numbered paragraph "2," as follows:

2. The X-ray operator, other Staff staff, and ancillary personnel, and other persons required for the medical procedure shall be protected from the ~~direct scatter~~ scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

ITEM 29. Amend subrule **41.1(3)**, paragraph "a," subparagraph (7), introductory paragraph, as follows:

(7) Individuals shall not be exposed to the useful beam ~~except for healing arts purposes and unless such exposure has been~~ unless (1) there is a previously established professional relationship with the 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, which includes a physical examination unless it is otherwise clinically appropriate; and (2) a written order for the radiation exposure has been issued by the individual in (1). The written order may be issued after the exposure that is the result of an emergency or surgery setting. This provision specifically prohibits deliberate exposure for the following purposes:

ITEM 30. Amend subrule **41.1(3)**, paragraph "a," subparagraph (8), numbered paragraph "3," as follows:

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)"a"(5)"2";

ITEM 31. Amend subrule **41.1(3)**, paragraph "a," subparagraph (11), as follows:

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified applicant shall notify the agency in writing within five calendar days.

ITEM 32. Amend subrule **41.1(3)**, paragraph "a," subparagraph (12), as follows:

(12) Fluoroscopic equipment shall be used only under the direct supervision of a licensed practitioner. Fluoroscopy shall not be used as a substitute for radiography or in lieu of proper anatomical positioning/centering procedures prior to radiographic studies.

ITEM 33. Amend subrule **41.1(3)**, paragraph "f," subparagraph (1), numbered paragraph "2," as follows:

2. Film shall be ~~developed~~ processed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom.

ITEM 34. Amend subrule **41.1(3)**, paragraph "f," subparagraph (2), numbered paragraph "1," as follows:

1. Films shall be ~~developed~~ processed in accordance with the time-temperature relationships recommended by the film manufacturer.

ITEM 35. Amend subrule **41.1(3)** by adopting new paragraph "g" as follows:

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

ITEM 36. Amend subrule **41.1(5)**, paragraph "c," subparagraph (1), numbered paragraph "1," the second bulleted paragraph, as follows:

- 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) 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be

operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

ITEM 37. Amend subrule **41.1(5)**, paragraph "c," subparagraph (1), numbered paragraph "2," introductory paragraph and second bulleted paragraph, as follows:

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ~~1.3 mC/kg (5 roentgens)~~ 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- ~~When an optional high level control is activated~~ When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

ITEM 38. Amend subrule **41.1(5)**, paragraph "c," subparagraph (1), by rescinding numbered paragraph "4" and adopting new numbered paragraphs "4" to "6" as follows:

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)"c"(1)"3";
- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)"c"(1)"3."

ITEM 39. Amend subrule **41.1(5)**, paragraph "f," subparagraph (4), as follows:

(4) 20 centimeters for ~~image intensified~~ mobile fluoroscopes used for specific surgical application.

ITEM 40. Amend subrule **41.1(6)**, paragraph "a," subparagraph (5), introductory paragraph, as follows:

(5) X-ray systems other than those described in 41.1(6)"a"(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

ITEM 41. Amend subrule **41.1(6)**, paragraph "b," subparagraph (1), as follows:

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

ITEM 42. Amend subrule **41.1(6)**, paragraph "b," subparagraph (2), numbered paragraph "2," introductory paragraph, as follows:

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

ITEM 43. Rescind subrule **41.1(6)**, paragraph "d," and adopt the following **new** paragraph in lieu thereof:

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

ITEM 44. Amend subrule **41.1(6)**, paragraph "e," as follows:

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed the rate of 2 milliroentgens (0.516 $\mu\text{C}/\text{kg}$) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

ITEM 45. Amend subrule **41.1(6)**, paragraph "g," subparagraph (2), as follows:

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliamperere-seconds product, in units of $\text{C kg}^{-1} \text{mAs}^{-1}$ (or mR/mAs) mR/mAs ($\text{C kg}^{-1} \text{mAs}^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_x \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

ITEM 46. Amend subrule **41.1(6)**, paragraph "h," subparagraph (1), by adopting **new** numbered paragraph "3" as follows:

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

ITEM 47. Amend subrule **41.1(11)**, paragraph "a," by rescinding the definitions of "computed tomography dose index," "contrast scale," "CT number," and "noise" and adopting the following **new** definitions in lieu thereof:

"Computed tomography dose index" means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

$D(z)$ = Dose at position z .

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around $z = 0$ and that, for a multiple tomogram system, the scan increment between adjacent scans is nT .

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{\text{CS}} = \frac{(\mu_x - \mu_w)}{\overline{(\text{CTN})_x} - \overline{(\text{CTN})_w}}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$\overline{(\text{CTN})_x}$ = of the material of interest.

$\overline{(\text{CTN})_w}$ = of water.

"CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

"Noise" means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

\overline{CS} = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

ITEM 48. Amend subrule **41.1(11)**, paragraph "d," subparagraph (1), numbered paragraph "1," as follows:

1. All CT X-ray systems ~~installed after the effective date of these rules and those systems not previously surveyed~~ shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

ITEM 49. Amend subrule **41.1(11)**, paragraph "d," subparagraph (2), numbered paragraph "6," as follows:

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the ~~CTDI~~ CTDI^{3/} along the two axes specified in 41.1(11)"d"(2)"4" shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)"d"(3) shall be made.

ITEM 50. Amend subrule **41.2(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January~~ May 1, 2003.

ITEM 51. Amend subrule **41.2(4)**, paragraph "e," as follows:

e. Before adding to or changing the ~~areas of use or~~ address or addresses of use identified in the application or on the license; and

ITEM 52. Amend subrule **41.2(10)**, paragraph "b," as follows:

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety ~~office~~ officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

ITEM 53. Amend subrule **41.2(11)**, paragraph "a," subparagraph (5), as follows:

(5) Require that only those individuals specifically trained in accordance with 641—Chapter 42 as applicable, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and be visible to the public.

ITEM 54. Amend subrule **41.2(14)** by adopting new paragraph "f" as follows:

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of by-product material or radiation from by-product material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)"f"(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)"f"(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14)"f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any

appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:

- Name of the pregnant individual or the nursing child who is the subject of the event; and

- Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

ITEM 55. Rescind and reserve subrule **41.2(80)**.

ITEM 56. Amend subrule **41.2(87)** by adopting **new** paragraph "h" as follows:

h. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

ITEM 57. Adopt **new** subrule **41.2(88)** as follows:

41.2(88) Other medical uses of by-product material or radiation from by-product material. A licensee may use by-product material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C) (e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

ITEM 58. Amend subrule **41.6(1)** as follows:

Amend the following definition:

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

Adopt the following **new** definition in alphabetical order:

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

ITEM 59. Amend subrule **41.6(2)**, paragraph "e," as follows:

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than ~~60 days~~ 14 months after initial mammography authorization and at least annually thereafter.

ITEM 60. Amend subrule **41.6(3)**, paragraph "a," subparagraph (2), numbered paragraph "1," as follows:

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~~ read 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 between the two. The facility will choose one of these dates to determine the 24-month period;

ITEM 61. Amend subrule **41.6(5)**, paragraph "k," subparagraph (5), numbered paragraph "1," as follows:

Rescind the first bulleted paragraph.

Amend the second bulleted paragraph as follows:

- ~~After October 28, 2002, the~~ 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 thickness over the kVp range used clinically in the facility.

ITEM 62. Amend subrule **41.6(5)**, paragraph "k," subparagraph (5), numbered paragraph "3," as follows:

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~~ Facilities shall evaluate focal spot condition only by determining the system resolution.

ITEM 63. Amend subrule **41.6(5)**, paragraph "k," subparagraph (5), numbered paragraph "10," first bulleted paragraph, as follows:

- The system shall be capable of producing a minimum output of ~~513~~ 800 milliRoentgen (mR) per second (~~4.5~~ 7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector. ~~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.~~

ITEM 64. Amend subrule **41.6(7)**, paragraph "b," as follows:

b. Equipment operators shall ~~wear personnel monitors to measure their radiation exposure~~ be monitored in accordance with 641—40.37(136C).

ITEM 65. Amend subrule **41.7(2)**, paragraph "e," as follows:

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than ~~60 days~~ 14 months after initial authorization and at least annually thereafter.

ITEM 66. Amend subrule **41.7(4)**, paragraph "b," subparagraph (2) as follows:

(2) On or after July 1, 1998, have performed one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified to perform stereotactically guided breast biopsy system physics surveys. Have at least one

stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met; and three hours of continuing education in stereotactically guided breast biopsy system physics every three years after the initial qualifications are met.

ITEM 67. Amend subrule **41.7(4)** by adopting new paragraph "c" as follows:

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and

(2) Have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics in the previous 36 months after the initial qualifications are met.

ITEM 68. Amend subrule **41.7(5)**, paragraph "c," as follows:

c. Maintenance of proficiency and continuing education requirements.

(1) Thereafter, Have performed an average of at least 12 stereotactically guided breast biopsies per year after initial qualifications are met or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a qualified physician or radiologic technologist.

(2) Have at least three hours of continuing education in stereotactically guided breast biopsy in the previous 36 months after initial qualifications are met.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures 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 between the two. The requirements of 41.6(3)"b"(4)"1" do not apply in this case.

ITEM 69. Amend subrule **41.7(7)** as follows:

Amend paragraph "d," subparagraph (2), as follows:

(2) Visual checklist (~~weekly~~ monthly).

Adopt new paragraph "f" as follows:

f. Additional evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

ITEM 70. Amend **641—Chapter 41, Appendix C**, by adopting new numbered paragraphs "15" to "17" as follows:

15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.

17. The dates of the screening to include beginning and ending dates.
18. A copy of IRB for a research project or information justifying the research project.

ITEM 71. Amend subrule **42.1(2)**, definitions of "diagnostic radiographer," "lower extremities," and "upper extremities," as follows:

"Diagnostic radiographer" means an individual, other than a licensed practitioner or ~~dental radiographer~~ podiatric or dental assistant with radiography qualification, who applies X-radiation to the human body for diagnostic purposes while under the supervision of a licensed practitioner or registered nurse registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152. The types are as follows:

1. "General diagnostic radiographer" applies X-radiation to any part of the human body.
2. "Limited diagnostic radiographer" applies X-radiation to not more than three of the following body parts: chest, extremities (upper and lower), spine, or sinus. This individual is restricted to performing radiography in that area of the facility specifically designed for X-ray. This individual may not perform pediatric radiography (children under three years of age) without additional training in pediatric radiography taken as a part of the basic limited training or a specifically approved training program (see 42.2(6)).

3. "Limited in-hospital radiographer" applies X-radiation as permitted in 42.3(1)"c."

"Lower extremities" refers to those body parts from the distal phalanges of the foot to the head of the femur and its articulation with the pelvic girdle as taught in the approved limited radiographer curriculum. True hip radiographs are prohibited under this category for limited diagnostic radiographers. This definition applies to 641—Chapter 42 only.

"Upper extremities" refers to those body parts from the distal phalanges of the hand to the head of the humerus. These projections may include the acromioclavicular or glenoid-humeral areas as taught in the approved limited radiographer curriculum. True shoulder radiography that includes both distal and proximal ends of the clavicle is prohibited under this category for limited diagnostic radiographers. This definition applies to 641—Chapter 42 only.

ITEM 72. Amend subrule **42.2(2)**, introductory paragraph, as follows:

42.2(2)Disciplinary grounds and actions. The procedures for administrative enforcement actions are found in 641—38.9(136C). The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying of fines:

ITEM 73. Amend subrule **42.2(2)**, paragraph "e," as follows:

e. Any action that the department determines may jeopardize the public, other staff, or certificate holder's health and safety. These actions shall include but not be limited to:

- (1) Any medical condition which may impair or limit the individual's ability to perform radiography;
- (2) Activity related to illegal or improper use of drugs or other chemical substances;
- (3) A misdemeanor or felony which may impair or limit the individual's ability to perform radiography;
- (4) Any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity.

ITEM 74. Amend subrule **42.2(3)**, paragraph "e," as follows:

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. Individuals authorized for mammography must meet the records requirements in 641—41.6(136C) and 641—41.7(136C).

ITEM 75. Amend subrule **42.2(7)** as follows:

42.2(7)Requirements for operators of dual imaging devices. When a unit is operated as a nuclear medicine imaging device, the operator must have a permit to practice as a nuclear medicine technologist and meet the requirements of 641—42.4(136C). When the unit is operated as a radiologic technology imaging device, the operator must have a permit to practice as a general diagnostic radiographer and meet the requirements of 641—42.3(136C). When a unit is operated in dual mode, the operator must have a permit to practice as a nuclear medicine technologist.

ITEM 76. Adopt **new** subrule **42.2(8)** as follows:

42.2(8)Examinations. All individuals seeking certification under 641—Chapter 42 must pass a written examination within six months of the date of the initial certification. The temporary six month permit will be issued to allow the individual to practice under supervision of a licensed practitioner, an authorized user listed on a radioactive materials license, or a permitted individual with the permit in the same or higher category. The individual will be issued an annual permit upon passing the examination. Any individual failing to pass the examination within six months will be suspended from performing the procedures allowed on the temporary permit until the examination is passed.

ITEM 77. Amend subrule **42.3(3)**, paragraph "a," introductory paragraph, as follows:

a. All individuals seeking to perform diagnostic radiography must, in addition to subrule 42.3(1), take and satisfactorily pass a written examination within six months of the ~~date of the initial certification~~ issuance date of the temporary certification. Examination must include the following subject matter for each category of radiographer:

ITEM 78. Amend subrule **42.4(3)**, paragraph "d," as follows:

d. Any individual holding a temporary certification must successfully complete an approved examination within ~~one year~~ six months of the issuance date of the temporary certification.

ITEM 79. Amend subrule **42.5(3)**, paragraph "d," as follows:

d. Any individual holding a temporary certification must successfully complete an approved examination within ~~one year~~ six months of the ~~date of completion of the training~~ issuance date of the temporary certification.

ITEM 80. Amend subrule **45.1(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January~~ May 1, 2003.

ITEM 81. Amend subrule **45.1(2)**, definitions of "radiographer trainee," "radiographer trainer (instructor)," and "radiographic personnel," as follows:

~~"Radiographer trainee~~ Radiographer's assistant" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)"a" and who uses sources of radiation and related handling tools or radiation survey instruments under the direct supervision of a radiographer trainer.

~~"Radiographer trainer (instructor)"~~ means any individual who instructs and supervises ~~radiographer trainees~~ radiographer's assistants during on-the-job training and who meets the requirements of 45.1(10)"c."

~~"Radiographic personnel"~~ means any radiographer or ~~radiographer trainee~~ radiographer's assistant.

ITEM 82. Amend subrule **45.1(6)** as follows:

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.

ITEM 83. Amend subrule **45.1(10)**, paragraph "a," introductory paratraphy, as follows:

a. ~~Radiographer trainee~~ Radiographer's assistant requirements. No licensee or registrant shall permit any individual to act as a ~~radiographer trainee~~ radiographer's assistant, as defined in this chapter, until:

ITEM 84. Amend subrule **45.1(11)** as follows:

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~~ radiographer's assistant to ensure that these rules, license requirements, and the licensee's or registrant's operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and ~~radiographer trainee~~ radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or ~~radiographer trainee~~ radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or ~~radiographer trainee~~ radiographer's assistant must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can next participate in a radiographic operation.

c. and d. No change.

ITEM 85. Amend subrule **45.1(12)**, paragraph "b," subparagraph (1), as follows:

(1) No licensee or registrant shall permit an individual to act as a radiographer, ~~radiographer trainee~~ radiographer's assistant, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically stimulated luminescent device (OSL device) or a thermoluminescent dosimeter (TLD) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

ITEM 86. Amend subrule **45.1(13)**, introductory paragraph, as follows:

45.1(13) Supervision of ~~radiographer trainee~~ radiographer's assistant. Whenever a ~~radiographer trainee~~ radiographer's assistant 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~~ radiographer's assistant shall be under the direct supervision of a radiographer instructor. The direct supervision must include:

ITEM 87. Amend subrule **45.1(17)**, paragraphs "c" and "e," as follows:

c. Each ~~radiographer trainee~~ radiographer's assistant at a job site shall possess a valid trainee status card issued by the agency.

e. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 88. Amend subrule **45.2(4)**, paragraphs "b" and "c," as follows:

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a ~~radiographer trainee~~ radiographer's assistant, the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 89. Amend subrule **45.3(2)**, paragraph "a," as follows:

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~~ radiographer's assistant, 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~~ radiographer's assistant.

ITEM 90. Amend subrule **45.3(6)**, paragraphs "c" and "e," as follows:

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~~ radiographer's assistant. If one of the personnel is a ~~radiographer trainee~~ radiographer's assistant, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Except for the situation of a radiographer trainer with a trainee, radiography shall not be performed if only one qualified individual is present.

e. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 91. Amend subrule **45.6(17)** by relettering paragraph "b" as "c" and adopting **new** paragraph "b" as follows:

b. The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

~~b~~ c. Personnel monitoring records and bioassay results shall be maintained for inspection until the agency authorizes disposition.

ITEM 92. Amend **641—Chapter 45, Appendix A**, title and the first sentence of the introductory paragraph, as follows:

CHAPTER 45—APPENDIX A
SUBJECTS FOR INSTRUCTION OF
RADIOGRAPHER TRAINEES RADIOGRAPHER'S ASSISTANTS

Training provided to qualify individuals as ~~radiographer trainees~~ radiographer's assistants in compliance with 45.1(10) shall be presented on a formal basis.

Jane Colavecchi, Acting Director
Department of Public Health

Date