

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," Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following itemize the changes.

Items 1, 11, 31, 61, and 93 amend the rules to reflect current federal regulations.

Items 2, 32, and 94 amend definitions to meet Nuclear Regulatory Commission (NRC) compatibility requirements.

Item 3 rescinds subrule 38.3(2) and replaces it with updated language to meet NRC compatibility requirements.

Items 4, 10, 26, 39, and 68 correct or change wording for clarity.

Item 5 prohibits scanning for nonmedical purposes because of exposure factors.

Item 6 adds a fee for mammography accreditation in order to cover the cost of the review.

Item 7 adds a fee for a new category of permit, the radiologist assistant.

Item 8 amends the fee for transportation of radioactive material across the state in order to cover the cost of the escort and emergency training.

Item 9 allows an exemption from fees in exchange for certain services used by the Agency.

Items 12 and 13 clarify the requirements a facility must meet in order to be registered or licensed. This clarification particularly affects companies operating mobile vans.

Item 14 adds new language for license exemptions to meet NRC compatibility requirements.

Items 15, 16, 17, 18, 19, 21, 22, 24, 28, and 30 amend rules governing general licensed radioactive material to meet NRC compatibility requirements.

Items 20 and 29 add new language governing general licensed radioactive material to meet NRC compatibility requirements.

Items 23, 25, 27, 53, 65, 91, and 118 rescind provision that are duplicated in another rule or no longer apply.

Items 33, 37, 54, and 56 update language to meet NRC compatibility requirements.

Items 34, 35, 36, 47, 48, 49, 50, 51, 52, and 59 are amended to remove references to forms no longer available from the Agency. These forms are standard industrywide and easily available from other sources.

Items 38, 40, 41, 42, 43, 44, 55, 57, and 58 add or correct language governing radiation exposure to meet NRC compatibility requirements.

Items 45 and 46 add language regarding securing radioactive material.

Item 60 changes posting requirements for certain documents.

Item 62 adds language to allow the citing of violations for equipment that are not covered in other rules.

Item 63 removes wording to allow verbal orders when the doctor is not in the room.

Item 64 adds language to require x-ray processors to be in good working order.

Item 66 removes language that is no longer needed due to industry standards.

Item 67 adds language to limit which individuals may administer radioactive materials.

Item 69 adds a paragraph to update requirements for a radiation therapy physicist in order to meet NRC compatibility requirement.

Item 70 revises language for written directives in order to meet NRC compatibility requirements.

Items 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, and 83 amend mammography rules for clarity and federal compliance.

Item 84 adds language to allow a screening program for cardiac scoring.

Item 85 adds a definition for a new category of certification and removes language from a definition that is no longer applicable.

Item 86 clarifies and adds language to expand the Agency's authority to sanction certification holders.

Item 87 adds continuing education requirements for a new category of certification.

Item 88 clarifies requirements for individuals submitting continuing education courses for review.

Item 89 clarifies and adds language to accept additional testing organizations. These organizations are already included in Agency policy.

Item 90 removes testing organizations that are no longer recognized as providing approved certification examinations.

Item 92 adds requirements for a new certification, radiologist assistant.

Items 95, 96, 97, 98, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 116, 117, and 119 amend rules for industrial radiography to meet NRC compatibility requirements.

Items 99 and 101 add new language for training of industrial radiographers to meet NRC compatibility requirements.

Item 115 rescinds old language and adds new language to meet NRC compatibility requirements for leak testing.

Items 120 and 121 amend and add language to require the posting of negative health effects in tanning facilities.

Item 122 adds a requirement that facility operators instruct consumers about the need to wear protective eyewear. This requirement is in Agency policy.

Items 123 and 124 add language to allow the Agency to proceed with certain disciplinary actions.

Item 125 adds a new appendix in conjunction with Items 121 and 122.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on February 2, 2005 as **ARC 3964B**. A public hearing was held on February 22, 2005. No one attended the hearing. Three sets of written comments were received and reviewed, and changes were incorporated as appropriate. The changes made from the Notice of Intended Action are as follows:

1. In Item 5, the following sentence, "Whole-body scanning devices shall not be used on humans for nonmedical purposes," was changed to read, "Radiation from radiation-

emitting machines or radioactive materials shall not be used on humans for nonmedical purposes." The change expands the rule to place restrictions on all radiation-emitting machines or radioactive materials.

2. In Item 43, in paragraph 40.37(1)"b," the phrase, "0.15 (1.5 mSv)," was replaced with, "0.15 rem (1.5 mSv)." This was an omission.

3. In Item 67, the following phrase, "Iowa licensed physician," was added to allow licensed physicians to administer radiopharmaceuticals under the supervision of an authorized user. The following phrase, "for nuclear medicine technologists or radiation therapists," was added to indicate that only these individuals are required to post a permit to practice. These changes are for clarification. The paragraph now reads as follows:

(5) Require that only those individuals specifically training in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa licensed physician and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects. The individual's permit to practice for nuclear medicine technologists or radiation therapists shall be posted in the immediate vicinity of the general work area and be visible to the public.

4. Item 82 was deleted and the remaining items were renumbered. Item 82 was submitted in error.

The State Board of Health adopted these amendments on March 9, 2005.

These amendments will become effective May 4, 2005.

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 ~~May 5, 2004~~ May 4, 2005.

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

Amend the following definitions:

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

"Individual monitoring" means the assessment of:

1. Dose equivalent by the use of ~~individual monitoring~~ devices designed to be worn by an individual or by the use of survey data; or

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

"Industrial radiography" means ~~a nondestructive testing method using ionizing radiation, such as gamma rays or X-rays, an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.~~

"Misadministration" means the administration of:

~~1- Radiation doses received from 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.~~

~~Administration of external beam radiation that results, or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician.~~

~~A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin; and either:~~

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

~~or~~

~~(2) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.~~

~~A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:~~

~~(1) An administration of the wrong treatment modality.~~

~~(2) An administration to the wrong patient or human research subject.~~

~~A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.~~

~~2. 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.~~

"Public dose" means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released ~~in accordance with~~ under 641—subrule 41.2(27) or from voluntary participation in medical research programs.

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

"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~~ encased in a capsule designed to prevent leakage or escape of the radioactive material.

"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, a physical survey of the location of radioactive material~~ and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

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

"Lot tolerance percent defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

ITEM 3. Rescind subrule **38.3(2)** and adopt **new** subrule **38.3(2)** as follows:

38.3(2) Persons using by-product material under certain Department of Energy and Nuclear Regulatory Commission contracts.

a. Except to the extent that NRC facilities or activities of the types subject to licensing pursuant to the Energy Reorganization Act of 1974 are involved, any prime contractor of the NRC is exempt from the license requirements of these rules and from the regulations of these rules to the extent that such contractor, under the contractor's prime contract with the NRC, manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material for:

(1) The performance of work for a department at the United States government-owned or government-controlled site, including the transportation of by-product material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(2) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(3) The use or operation of nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.

b. In addition to the foregoing exemptions and subject to the requirement for licensing of NRC facilities and activities pursuant to the requirements of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the NRC is exempt from the requirements for a license set forth in the Act and from the regulations in these rules to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses by-product material under the contractor's or subcontractor's prime contract or subcontract when the NRC determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

c. Carriers. Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from these rules to the extent that they transport or store radioactive material in the regular course of carriage for another or of storage incident thereto.

ITEM 4. Amend subrule **38.4(4)**, paragraph "a," as follows:

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

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent (see 1.)
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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.1. Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem. rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

ITEM 5. Amend rule **641—38.6(136C)** as follows:

641—38.6(136C) Prohibited uses. A hand-held fluoroscopic screen shall not be used with X-ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe-fitting fluoroscopic device shall not be used. Whole body scanning devices shall not be used on humans for non-medical purposes.

ITEM 6. Amend subrule **38.8(1)** by adopting new paragraph "f" as follows:

f. All Iowa-accredited facilities providing mammography services in Iowa must submit a \$200 accreditation fee for initial accreditation and each reaccreditation.

ITEM 7. Amend subrule **38.8(6)**, introductory paragraph, as follows:

38.8(6) Certification fees. Diagnostic radiographers, radiologist assistants, 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:

ITEM 8. Amend subrule **38.8(11)**, paragraph "a," subparagraphs (1), (2), and (3), as follows:

(1) ~~\$1750~~ 1800 per highway cask for each truck shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof. Single cask truck shipments are subject to a surcharge of ~~\$15~~ 20 per mile for every mile over 250 miles traveled.

(2) ~~\$1250~~ 1300 for the first cask and ~~\$400~~ 125 for each additional cask for each rail shipment of spent nuclear fuel, high-level radioactive waste or transuranic waste traversing the state or any portion thereof.

(3) ~~\$400~~ \$125 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 9. Amend rule **641—38.8(136C)** by adopting new subrule **38.8(12)** as follows:

38.8(12) Fee waiver. Any fee may be waived in exchange for services (low-level waste disposal, radiation detection instrument calibration, instrument repair, sample analysis, etc.) provided to the agency. The waiver may only occur as a result of a 28E agreement between the parties.

ITEM 10. Amend subrule **38.10(1)**, introductory paragraph, as follows:

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~~ may not:

ITEM 11. Amend subrule **39.1(3)** as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 5, 2004~~ May 4, 2005.

ITEM 12. Amend subrule **39.3(2)**, paragraph "a," as follows:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a ~~permanent office located in Iowa that has a non-wireless telephone, employee and equipment, and storage for records regarding the equipment and operator certification.~~ storage area located in Iowa where records of equipment maintenance and quality assurance, personnel monitoring, and personnel certification must be kept for review during an inspection. The records may be stored on a van, if appropriate. An Iowa mailing address is not required. Application for registration shall be completed on forms furnished by the agency and shall include the appropriate fee from 641—38.8(136C).

ITEM 13. Amend subrule **39.4(1)**, paragraph "b," as follows:

b. An Iowa radioactive materials license requires that the person have a ~~permanent office storage area~~ in Iowa where records are maintained pertaining to licensed activities, equipment maintenance and quality assurance, personnel monitoring, and personnel certification and where material can be stored. The records may be stored on a van, if appropriate. The office must have at least one full-time employee and a telephone storage area must be assessable during inspections. An Iowa mailing address is not required.

ITEM 14. Amend subrule **39.4(3)**, paragraph "a," by adopting new subparagraphs (4) and (5) as follows:

(4) This rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(5) A manufacturer, processor, or producer of a product or material in an agreement state is exempt from the requirements for a license and from these rules to the extent that the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of the requirements in Appendix A of this chapter and introduced into the product or material by a licensee holding a specific license issued by an agreement state or the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

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

(3) This paragraph (39.4(3)"b") does not authorize for purposes of commercial distribution, the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

ITEM 16. Amend subrule **39.4(3)**, paragraph "c," subparagraph (1), as follows:

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

ITEM 17. Amend subrule **39.4(3)**, paragraph "c," subparagraph (1), numbered paragraph "9," as follows:

9. Ionizing radiation measuring ~~or detection devices~~ instruments, for purposes of internal calibration or standardization, containing one or more sources of radioactive material, provided that:

- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each device contains no more than ten exempt quantities. For purposes of this requirement, a device's source(s) may contain either one type of or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or
- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)"c"(1)"9."

ITEM 18. Amend subrule **39.4(3)**, paragraph "c," subparagraph (2), numbered paragraph "1," as follows:

1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, ~~or produce~~, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product to persons who are exempt from regulatory requirements for use under these rules. Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use according to this paragraph, shall apply for a license which states that the product may be transferred by the licensee to persons exempt from this paragraph. The exemption in 39.4(3)"c"(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

ITEM 19. Amend subrule **39.4(3)**, paragraph "c," subparagraph (3), numbered paragraph "1," as follows:

1. Except for persons who manufacture, process, ~~or produce~~, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from 641—Chapters 38, 39, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, ~~provided that detectors containing radioactive material shall have been~~ and manufactured, imported, or processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.27 of 10 CFR Part 32; or a licensing state pursuant to

39.4(29)"c," which authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements product for use under this rule.

ITEM 20. Amend subrule **39.4(3)**, paragraph "c," subparagraph (3), by adopting new numbered paragraph "4," as follows:

4. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to 39.4(3)"c"(3)"1," shall apply for a license which states that the product may be initially transferred by the licensee to persons exempt from these rules, the regulations of the U.S. Nuclear Regulatory Commission, or equivalent rules of an agreement state.

ITEM 21. Amend subrule **39.4(3)**, paragraph "c," subparagraph (4), as follows:

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or ~~imported~~ initially transferred for sale or distribution in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture or initial transfer for sale or distribution of any resins containing scandium-46.

ITEM 22. Amend subrule **39.4(26)**, paragraph "g," introductory paragraph, as follows:

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 released for unrestricted use. Before licensed activities are transferred or assigned to another licensee, the licensee shall transfer all records described in this subrule to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

ITEM 23. Rescind and reserve subrule 39.4(29), paragraph "b."

ITEM 24. Rescind subrule **39.4(29)**, paragraph "c," and adopt new paragraph "c" as follows:

c. Resins containing scandium-46 and designed for sand consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution. An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to 39.4(3)"c"(4) will be approved if the applicant satisfies the general requirements of 39.4(25) and the criteria of Sections 32.16 of 10 CFR Part 32.

ITEM 25. Amend subrule **39.4(29)**, paragraph "h," subparagraph (2), by rescinding the second numbered paragraph and renumbering subsequent paragraphs "3" to "8" as "2" to "7."

ITEM 26. Amend subrule **39.4(29)**, paragraph "h," subparagraph (4), numbered paragraph "1," as follows:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation

therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority an agreement state.

Name of manufacturer

ITEM 27. Rescind subrule 39.4(29), paragraph "h," subparagraph (4), numbered paragraph "2."

ITEM 28. Amend subrule **39.4(29)**, paragraph "i," as follows:

i. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture ~~and distribute~~ or initially transfer ice detection devices containing strontium-90 to persons generally licensed under 39.4(22)"j" will be approved if the applicant satisfies the general requirements of 39.4(25) and the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32.

ITEM 29. Amend subrule **39.4(29)** by adopting new paragraphs "n" and "o" as follows:

n. Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution. An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to 39.4(3)"c"(4) will be approved if:

- (1) The applicant satisfies the general requirements specified in 39.4(25);
- (2) The applicant satisfies the requirements of 10 CFR 32.17 or their equivalent.

o. Acceptance sampling procedures under certain specific licenses. A random sample shall be taken from each inspection lot of devices licensed under 39.4(29) for which testing is required and meet the requirements pursuant to 10 CFR 32.110.

ITEM 30. Amend subrule **39.4(33)**, paragraph "h," as follows:

h. Except as provided in 39.4(33)"i," licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. When the decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

ITEM 31. 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 ~~May 5, 2004~~ May 4, 2005.

ITEM 32. Amend subrule **40.2(2)**, definition of "derived air concentration (DAC)," as follows:

"Derived air concentration (DAC)" means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour) results in an intake of one ALI. ~~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.

ITEM 33. Amend subrule **40.17(1)** as follows:

40.17(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

ITEM 34. Amend subrule **40.19(3)**, paragraph "b," as follows:

b. Accept, as the record of lifetime cumulative radiation dose, ~~an up-to-date IDPH Form 588-2833 or equivalent~~ a form signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

ITEM 35. Amend subrule **40.19(4)** as follows:

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~~ the exposure history. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on ~~IDPH Form 588-2833 or equivalent~~ the report indicating the periods of time for which data are not available.

b. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded ~~on 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.

ITEM 36. Amend subrule **40.19(6)** as follows:

40.19(6) The licensee or registrant shall retain the records ~~on IDPH Form 588-2833 or equivalent~~ in 641—40.19(136C) until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing ~~IDPH Form 588-2833 or equivalent~~ any record for this subrule for three years after the record is made.

ITEM 37. Amend rule **641—40.21(136C)** as follows:

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).

ITEM 38. Amend subrule **40.22(4)** as follows:

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)~~ 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

ITEM 39. Amend subrule **40.26(1)** as follows:

40.26(1) Each licensee or registrant shall conduct operations so that:

a. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage ~~in accordance with~~ under 641—40.72(136C); and

b. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released ~~in accordance with~~ under 641—subrule 41.2(27), does not exceed 0.002 rem (0.02 millisievert) in any one hour.

ITEM 40. Amend subrule **40.27(1)** as follows:

40.27(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 40.26(136C).

ITEM 41. Amend subrule **40.28(1)** as follows:

40.28(1) The criteria in this rule apply to the decommissioning of facilities licensed under 641—Chapter 39, and to the release of part of a facility or site for unrestricted use, as well as other facilities subject to the agency's jurisdiction under Iowa Code chapter 136C.

ITEM 42. Amend subrule **40.28(3)** as follows:

40.28(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this chapter, or after part of a facility or site has been released for unrestricted use in accordance with this chapter, the agency will require additional cleanup only if, based on new information, it determines that the criteria of this chapter were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

ITEM 43. Amend subrule **40.37(1)** as follows:

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 deep dose equivalent dose in excess of 10 percent of any of the applicable limits in 40.21(136C) or 40.22(136C) 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (1 mSv); and

c. Individuals entering a high or very high radiation area; ~~;~~

d. Individuals working with medical fluoroscopic equipment; ~~and~~

e. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv).

ITEM 44. Amend subrule **40.37(2)** as follows:

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);~~ 0.1 rem (1 mSv); and

c. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

ITEM 45. Amend rule **641—40.55(136)**, paragraph "a," as follows:

a. The licensee or registrant shall secure licensed or registered radioactive material that are stored in controlled or unrestricted areas from unauthorized removal or access.

ITEM 46. Amend rule **641—40.55(136)** by adopting new paragraph "e" as follows:

e. Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

ITEM 47. Amend subrule **40.82(3)** as follows:

40.82(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records ~~on IDPH Form 588-2833 or 588-2834 or equivalent~~ required in 641—40.82 or shall make provisions with the Agency for transfer to the Agency.

ITEM 48. Amend subrule **40.84(1)** as follows:

40.84(1) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 40.19(136C) ~~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~~ the record required in 40.84(136C) for three years after the record is made.

ITEM 49. Amend subrule **40.84(2)** as follows:

40.84(2) Upon termination of the license or registration, the licensee or registrant shall permanently store records ~~on IDPH Form 588-2833 or equivalent~~ required in 40.84(136C) or shall make provisions with the Agency for transfer to the Agency.

ITEM 50. Amend subrule **40.85(3)** as follows:

40.85(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records ~~on IDPH Form 588-2833 or equivalent~~ required in 40.85(136C) or shall make provisions with the Agency for transfer to the Agency.

ITEM 51. Amend subrule **40.86(3)** as follows:

40.86(3) Record-keeping format. The licensee or registrant shall maintain the records specified in 40.86(1) ~~on IDPH Form 588-2834, 588-2833, or equivalent in accordance with the instructions for IDPH Form 588-2834, 588-2833, or equivalent or in clear and legible records containing all the information required by IDPH Form 588-2834, 588-2833, or equivalent form.~~

ITEM 52. Amend subrule **40.86(6)** as follows:

40.86(6) Retention after termination. Upon termination of the license or registration, the licensee or registrant shall permanently store records ~~on IDPH Form 588-2833, 588-2834, or equivalent~~ required in 40.86(136C) or shall make provision with the Agency for transfer to the Agency.

ITEM 53. Rescind subrule 40.95(1), paragraph "d."

ITEM 54. Amend subrule **40.96(1)**, paragraph "a," subparagraphs (2) and (3), as follows:

(2) ~~An eye A lens~~ A lens dose equivalent of 75 rem (0.75 Sv) or more; or

(3) A shallow dose equivalent to the skin or extremities ~~or a total organ dose equivalent~~ of 250 rad (2.5 Gy) or more; or

ITEM 55. Amend subrule **40.96(1)**, paragraph "b," as follows:

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the ~~occupational ALI~~ annual limit on intake. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

ITEM 56. Amend subrule **40.96(2)**, paragraph "a," subparagraphs (2) and (3), as follows:

(2) ~~An eye A lens~~ A lens dose equivalent exceeding 15 rem (0.15 Sv); or

(3) A shallow dose equivalent to the skin or extremities ~~or a total organ dose equivalent~~ exceeding 50 rem (0.5 Sv); or

ITEM 57. Amend subrule **40.97(1)**, paragraph "b," by adopting **new** subparagraph (6) as follows:

(6) The limits for an embryo/fetus of a declared pregnant woman in 40.22(136C).

ITEM 58. Amend subrule **40.97(3)** as follows:

40.97(3) All licensees or registrants who make reports pursuant to 40.97(1) ~~shall submit the report in writing~~ to the Agency shall also provide a copy of the report to the individual. Transmittal shall be at the same time as the transmittal to the Agency.

ITEM 59. Amend subrule **40.100(2)** as follows:

40.100(2) Each licensee or registrant in a category listed in 40.100(1) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 40.36(136C) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. ~~The licensee or registrant shall use IDPH Form 588-2834 or equivalent or electronic media containing all the information required by IDPH Form 588-2834.~~

ITEM 60. Amend subrule **40.110(4)** as follows:

40.110(4) Agency documents posted pursuant to 40.110(1)"d" shall be posted within ~~five~~ two working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within ~~five~~ two working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

ITEM 61. Amend subrule **41.1(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 5, 2004~~ May 4, 2005.

ITEM 62. Amend subrule **41.1(3)**, paragraph "a," subparagraph (1), as follows:

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

ITEM 63. Amend subrule **41.1(3)**, paragraph "a," subparagraph (7), introductory paragraph, as follows:

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is ~~directly~~ supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

ITEM 64. Amend subrule **41.1(3)**, paragraph "f," subparagraph (2), by adopting **new** numbered paragraph "3," as follows:

3. All processing equipment shall be in good mechanical working order.

ITEM 65. Rescind subrule 41.1(4), paragraph "i."

ITEM 66. Amend subrule **41.1(5)**, paragraph "c," subparagraph (1), numbered paragraph "3," as follows:

3. Compliance with the requirements of 41.1(5)"c" shall be determined as follows: ~~movable grids and compression devices shall be removed from the useful beam during the measurement;~~

ITEM 67. 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 a nuclear medicine technologist or a radiation therapist, 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 68. Amend subrule **41.2(87)**, paragraph "a," subparagraph (4), and adopt new subparagraph (7) as follows:

(4) For teletherapy, ~~particle accelerator or X-ray~~: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(7) For therapeutic use of radiation machines, see 41.3(14);

ITEM 69. Amend subrule **41.3(6)** by adopting new paragraph "e" as follows:

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16)"a," 41.3(17)"c" and "d," and 41.3(18)"e" and "f" under the supervision of a radiation therapy physicist during the year of work experience.

ITEM 70. Rescind subrules **41.3(14)** and **41.3(15)** and adopt new subrules **41.3(14)** and **41.3(15)** as follows:

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and

2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

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

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

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;

2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual or individuals who received the administration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

(1) The registrant's name and the names of the individuals involved;

(2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

(3) A brief description of the event; why it occurred; and the effect, if any, on the individual;

(4) The actions, if any, taken or planned to prevent recurrence; and

(5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

ITEM 71. Amend subrule **41.6(2)**, paragraph "b," introductory paragraph and subparagraphs **(1)** and **(8)**, as follows:

b. Each facility wishing to perform mammography shall apply for agency ~~authorization~~ approval 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) agency-approved~~ mammography accreditation bodies. ~~An evaluation report issued by the American College of Radiology meets this requirement.~~

(8) Provisional ~~authorization~~ certification. A new facility beginning operation after September 30, 1994, is eligible to apply for a provisional ~~authorization~~ certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional ~~authorization~~ certification, a facility must meet the requirements of 641—41.6(136C). A ~~provisional authorization~~ Provisional certification 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.

ITEM 72. Amend subrule **41.6(2)**, paragraph "c," as follows:

c. Withdrawal or denial of mammography ~~authorization~~ certification.

(1) Mammography ~~authorization~~ certification 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~~ certification.

(2) The facility shall have opportunity for a hearing in connection with a denial or withdrawal of mammography ~~authorization~~ certification in accordance with 641—Chapter 173.

(3) An emergency order withdrawing ~~authorization~~ certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If ~~authorization~~ certification is withdrawn, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's ~~authorization~~ certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

ITEM 73. Amend subrule **41.6(2)**, paragraph "d," catchwords, as follows:

d. Reinstatement of mammography ~~authorization~~ certification.

ITEM 74. Amend subrule **41.6(2)**, paragraph "e," as follows:

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

ITEM 75. Amend subrule **41.6(2)**, paragraph "f," subparagraph (1), numbered paragraphs "1" and "2," as follows:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with ~~predominately fatty breasts~~ breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with ~~at least 75 percent~~ predominantly glandular breast tissue, and

ITEM 76. Amend subrule **41.6(2)**, paragraph "g," as follows:

g. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR ~~Parts 16 and~~ Part 900 which ~~have~~ has an effective date of April 28, 1999. Persons ~~authorized~~ certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

ITEM 77. Amend subrule **41.6(3)**, paragraph "a," subparagraph (4), numbered paragraph "1," the second bulleted paragraph, as follows:

- 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 at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)"a"(4)"1" shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This Agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90 day waiting period.

ITEM 78. Amend subrule **41.6(3)**, paragraph "b," subparagraph (2), introductory paragraph, as follows:

(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 after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

ITEM 79. Amend subrule **41.6(3)**, paragraph "b," by adopting **new** subparagraph (5) as follows:

(5) Consecutive, or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This Agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

ITEM 80. Amend subrule **41.6(5)**, paragraph "e," subparagraph (8), as follows:

(8) Image quality. The minimum image quality achieved at a ~~mammographic~~ mammography facility shall be the ability to observe the image of at least four 0.75-mm fibrils, three 0.32-mm ~~specks~~ speck groups, and three 0.75-mm masses from an ACR FDA-approved phantom or equivalent on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

ITEM 81. Amend subrule **41.6(5)**, paragraph "g," subparagraph (2), as follows:

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in ~~Appendix I~~ 41.6(5)"k." 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.

ITEM 82. Amend subrule **41.6(5)**, paragraph "k," subparagraph (7), numbered paragraph "2," as follows:

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~~ 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."~~

ITEM 83. Amend subrule **41.6(6)**, paragraph "t," subparagraph (1), as follows:

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

ITEM 84. Amend **641—Chapter 41, Appendix C**, numbered paragraph "4," as follows:

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

ITEM 85. Amend subrule **42.1(2)** as follows:

Amend the following definition:

"Special category course" means those programs still related to health care but indirectly related to diagnostic radiography, nuclear medicine technology, or radiation therapy. Such programs are: venipuncture, CPR, educator's programs, management programs, ~~tumor boards, equipment training,~~ personal improvement, for example.

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

"Radiologist assistant" means an advanced-level radiographer, other than a licensed practitioner, who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the diagnostic imaging environment. The radiologist assistant may exercise autonomy in decision making in the role of a primary caregiver with regard to patient assessment, patient management and in providing a broad range of radiology diagnostic and interventional services.

ITEM 86. Amend subrule **42.2(2)** as follows:

42.2(2) Disciplinary grounds and actions. The procedures for administrative enforcement actions are found in 641—38.9(136C) and 38.10(136C). The following shall be grounds for disciplinary action involving possible probation, suspension, ~~or~~ revocation, or denial of certification, or levying of fines or other sanctions:

a. Operating as a diagnostic radiographer, radiologist assistant, nuclear medicine technologist, or radiation therapist without meeting the requirements of this chapter.

b. Allowing any individual excluding a licensed ~~physician practitioner as defined in 641—38.2(136C)~~ to operate as a diagnostic radiographer, radiologist assistant, nuclear medicine technologist, or radiation therapist if that individual cannot provide proof of certification by the ~~department agency~~.

c. Failing to report to the ~~department~~ agency 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, radiologist assistant, 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. 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, nuclear medicine procedures, or radiation therapy;

(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, nuclear medicine procedures, or radiation therapy;

(4) Any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity;

(5) Being found guilty of incompetence or negligence during the certificate holder's performance as a certificate holder;

(6) Performing medical imaging, radiation therapy, or nuclear medicine procedures without either supervision or a written order of a licensed practitioner.

(7) Interpreting and rendering a diagnosis based on a diagnostic image for a physician, a patient, the patient's family, or the public.

f. Performing procedures not allowed under the individual's current certification.

g. Failing to pay fees or costs required to meet the requirements of this chapter. ~~The penalty for working without the required permit will be \$100 and suspension from performing radiography until the permit is issued.~~ Penalties for working without a permit will be considered on a case-by-case basis.

h. Failure to respond to an audit request or failure to provide proper documentation.

i. Submitting false information to a facility that might place the facility in noncompliance with 641—Chapters 38 to 41.

j. Violating any of the rules of 641—Chapters 38 to 41.

ITEM 87. Amend subrule **42.2(3)**, paragraph "a," by adopting the following **new** subparagraph (8):

(8) Radiologist assistant: proof of 24.0 clock hours with at least 12.0 hours in the subjects in 42.6(1)"c." The remaining hours may be in general radiography subjects.

ITEM 88. Amend subrule **42.2(3)**, paragraph "b," as follows:

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.~~

(1) Information must be submitted in writing and must provide sufficient detail to show that the course meets the relevancy requirements of these rules and the agency guidelines.

(2) Following its review, the department agency 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 agency 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.

(5) No continuing education credit is approved for passing a certification examination, hands-on practice, or mandatory reporting, ultrasound or MRI courses that are less than 50 percent directly related to radiography.

ITEM 89. Amend subrule **42.3(3)**, paragraph "c," as follows:

c. The department agency may accept, in lieu of its own examination, evidence of satisfactory performance in an examination given by an appropriate organization or testing service provided that the department agency finds the organization or service to be competent to examine applicants in the discipline of radiography. For purposes of this subrule, individuals ~~who are registered have passed as general diagnostic radiographers~~ the general radiography examination with the American Registry of Radiologic Technologists or American Registry of Clinical Radiography Technologists meet the testing requirements of 42.3(3). Individuals who have passed the limited radiography examination with the American Registry of Chiropractic

Radiography Technologists meet the testing requirements of 42.3(3) for limited radiography in spines and extremities.

ITEM 90. Amend subrule **42.4(1)**, as follows:

42.4(1) Specific eligibility requirements.

a. Any individual who is registered in nuclear medicine technology with the ~~following organizations may meet~~ American Registry of Radiologic Technologists meets the education and testing requirements of this rule.

~~(1) American Registry of Radiologic Technologists.~~

~~(2) Nuclear Medicine Technology Certification Board.~~

~~(3) American Society of Clinical Pathologists.~~

b. ~~Any individual, other than a licensed physician, who has completed all educational requirements of this rule but has not yet successfully completed the required examination will be issued temporary certification valid for one year from completion of a training program approved by the department.~~

ITEM 91. Amend subrule **42.5(1)** by rescinding and reserving paragraph "b."

ITEM 92. Amend **641—Chapter 42** by adopting the following new rule **42.6:**

641—42.6(136C) Specific eligibility requirements for radiologist assistant.

42.6(1) In addition to the requirements of 641—42.3(136C), any person seeking certification as a radiologist assistant shall:

a. Be eligible to be certified as a general radiographer in Iowa.

b. Have five years of experience as a general diagnostic radiographer.

c. Satisfactorily complete an advanced academic program approved by this agency.

Approved training shall include appropriate coursework, training, and experience in performing procedures, including but not limited to fluoroscopy, modified barium swallow, needle localization, needle aspiration, thoracentesis, arthrography, myelography, venography, angiography, and biopsy.

d. Satisfactorily complete the Certification Board for Radiology Practitioner Assistants (CBRPA) certification examination.

e. Upon completion of the above, apply for a permit to operate as a radiologist assistant.

42.6(2) Performance standards. A radiologist assistant:

a. May not interpret images, make diagnoses, or prescribe medications or therapies.

b. Shall:

(1) Provide a broad range of radiology health care services under the supervision of a licensed practitioner;

(2) Assess and evaluate the physiologic and psychologic responsiveness of each patient;

(3) Participate in patient management, including prescriptive powers for imaging procedures;

(4) Administer intravenous medications or contrast media, under the supervision of a licensed physician and record documentation in medical records;

(5) Perform fluoroscopic procedures, both dynamic and static;

(6) Perform specialized imaging procedures, including invasive procedures, after demonstrating competency and under the supervision of a licensed practitioner.

(7) Evaluate and screen medical images for normal versus abnormal and provide a technical report to the supervising licensed practitioner;

ITEM 93. 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 ~~May 5, 2004~~ May 4, 2005.

ITEM 94. Amend the following definitions in subrule **45.1(2)**:

"Certifying entity" means an independent certifying organization meeting the requirements of Appendix A in 10 CFR Part 34 or an agreement state meeting the requirements in Appendix A, Parts II and III of 10 CFR Part 34.

"Offshore platform radiography" means industrial radiography ~~performed on~~ conducted from an offshore platform or other structure over a body of water.

"Radiographic operations" means all activities associated with the presence of radioactive sources or radiation in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"Temporary job site" means any location where ~~industrial radiography is performed~~ radiographic operations are conducted and where licensed material may be stored other than the location(s) listed in a specific license or certificate of registration.

ITEM 95. Amend subrule **45.1(4)** as follows:

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 name of the individual made making the record, the radionuclide, number of curies or mass (for DU), and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for ~~agency inspection until disposal is authorized by the agency.~~ three years after they are made.

ITEM 96. Amend subrule **45.1(5)**, paragraph "b," subparagraph (2), as follows:

(2) Such that accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked;

ITEM 97. Amend subrule **45.1(7)**, paragraph "a," as follows:

a. Each licensee shall maintain ~~current~~ utilization logs of the use of each sealed source. The logs shall include:

(1) A unique ~~identification~~ description, which includes the make, model and serial number of each radiographic exposure device containing a sealed source, ~~and each sealed source or transport or storage container in which the sealed source is located~~;

(2) The identity and signature of the radiographer ~~using the sealed source to whom the sealed source is assigned~~;

(3) ~~Locations~~ The plant or site where each sealed source is used; and

(4) The date(s) each sealed source is removed from storage and returned to storage.

ITEM 98. Amend subrule **45.1(8)**, paragraph "b," as follows:

b. Each licensee or registrant shall have written procedures and conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, source changers, survey instruments, and associated equipment to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Replacement components shall meet design specifications. This program shall cover, as a minimum, the items in Appendix B of this chapter.

ITEM 99. Amend subrule **45.1(10)**, paragraph "a," subparagraph (1), by adopting new numbered paragraphs "5" and "6," as follows:

5. And developed competence to use, under the personal supervision of the radiographer, the licensee's or registrant's radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use;

6. And has demonstrated competence in the use of radiographic exposure devices, sources, survey instruments and associated equipment described in 45.1(10)"a"(1) by successful completion of a practical examination covering this material.

ITEM 100. Amend subrule **45.1(10)**, paragraph "b," subparagraph (1), numbered paragraph "3," as follows:

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments by successful completion of a practical examination covering this material;

ITEM 101. Amend subrule **45.1(10)**, paragraph "d," subparagraph (2), as follows:

(2) The RSO's qualifications shall include:

1. No change.

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. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and~~

4. Formal training in the establishment and maintenance of a radiation protection program.

5. The agency will consider alternatives when the RSO has either appropriate training or experience, or both, in the field of ionizing radiation and, in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

ITEM 102. Amend subrule **45.1(11)**, paragraph "c," as follows:

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

ITEM 103. Amend subrule **45.1(12)**, paragraph "d," as follows:

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~~ three years from the date of the event.

ITEM 104. Amend subrule **45.1(12)**, paragraph "e," as follows:

e. Reports received from the film badge, OSL device or TLD processor shall be kept for inspection by the agency until the agency ~~authorizes disposition~~ terminates the license.

ITEM 105. Amend subrule **45.1(12)**, paragraph "f," subparagraph (4), as follows:

(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~~ three years by the licensee or registrant for agency inspection.

ITEM 106. Amend subrule **45.1(13)**, introductory paragraph and paragraph "c," as follows:

45.1(13) Supervision of radiographer's assistant. Whenever a radiographer's assistant uses radiographic exposure devices, sealed sources or ~~related source handling tools associated equipment~~ or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the direct supervision of a radiographer instructor. The direct supervision must include:

c. The radiographer's direct observation of the ~~trainee's~~ radiographer's assistant's performance of the operations referred to in this subrule.

ITEM 107. Amend subrule **45.1(14)** as follows:

45.1(14) Access control.

a. During each industrial radiographic operation, a radiographer or radiographer's assistant shall maintain continuous, direct visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area or high radiation area, except:

(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 at permanent radiographic installations where all entryways are locked to protect against unauthorized or accidental entry and the requirements of 45.1(9) are met.~~

b. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.

ITEM 108. 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 of the sealed source, and shall~~ Either the exposure device or its container must be kept locked and, if applicable, the key removed, at all times when not under the direct surveillance of a radiographer or a radiographer's assistant except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to 45.3(6) at permanent radiographic installations as stated in 45.1(14). Each sealed source storage container and source changer ~~likewise shall be provided with~~ must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. and shall Storage containers and source changers must be kept locked (and if the lock is a keyed-lock, with the key removed at all times) when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

ITEM 109. Amend subrule **45.3(3)** by rescinding paragraph "a" and adopting new paragraph "a" as follows:

a. Labeling, storage, and transportation.

(1) The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording: "CAUTION RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or name of company)," or "DANGER."

(2) The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with 641—39.5(136C).

(3) Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(4) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

ITEM 110. Amend subrule **45.3(4)**, paragraph "a," as follows:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the ~~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.

ITEM 111. Amend subrule **45.3(4)**, paragraph "b," introductory paragraph, as follows:

b. In addition to the requirements specified in paragraph "a" of this subrule, the following requirements apply to radiographic exposure devices, source changers, source assemblies, sealed sources, and associated equipment.

ITEM 112. Amend subrule **45.3(4)**, paragraph "b," subparagraph (1), numbered paragraphs "2" to "4," as follows:

2. Activity and the date on which this activity was last measured;
3. Model number (or product code) and serial number of the sealed source;
4. Manufacturer's identity of the sealed source; and

ITEM 113. Amend subrule **45.3(4)**, paragraph "b," subparagraph (3), as follows:

(3) Modification of any radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

ITEM 114. Amend subrule **45.3(4)**, paragraph "c," introductory paragraph, as follows:

c. In addition to the requirements specified in paragraphs "a" and "b" of this subrule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or source changing:

ITEM 115. Rescind subrule **45.3(5)**, paragraphs "b," "c," and "d," and adopt new paragraphs "b," "c," and "d," as follows:

b. Leak testing requirements.

(1) Each licensee that uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by this agency. The wipe sample should be taken from the nearest accessible

point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by this agency to perform the analysis.

(2) The licensee shall maintain records of the leak tests results for sealed sources and devices containing depleted uranium (DU). The results must be stated in units of microrcuries (becquerels). The licensee shall retain each record for three years after it is made or until the source in storage is removed.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

c. Any test conducted under this subrule which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw from use the equipment involved and shall have it decontaminated and repaired or disposed of in accordance with agency rules. Within five days after obtaining the results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.

d. Each exposure device using (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the agency to perform the analysis. Should such testing reveal the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU-shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeds 12 months.

ITEM 116. Amend subrule **45.3(6)**, paragraph "c," 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's assistant. If one of the personnel is a radiographer's assistant, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. ~~Except for the situation of a radiographer trainer with a trainee, radiography~~ Radiography shall not be performed if only one qualified individual is present.

ITEM 117. Amend subrule **45.3(6)** by rescinding paragraph "e" and adopting new paragraph "e" as follows:

e. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation, unless specifically authorized by the agency.

ITEM 118. Amend subrule 45.6(3) by rescinding the definition of "field station."

ITEM 119. Amend **641—Chapter 45**, Appendix C, as follows:

CHAPTER 45—APPENDIX C
TIME REQUIREMENTS FOR RECORD KEEPING

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(4)	Receipt, transfer and disposal.	Until disposal is authorized by the agency. <u>3 years.</u>
45.1(5)	Survey instrument calibrations.	3 years.
45.3(5)	Leak tests.	3 years.
45.1(6)	Quarterly inventory.	3 years.
45.1(7)	Utilization logs.	3 years.
45.1(8)	Quarterly inspection and maintenance.	3 years.
45.1(9)	High radiation area control devices or alarm systems.	Until disposal is authorized by the agency.
45.1(10)	Training and testing records.	3 years.
45.1(12)	Pocket dosimeter readings.	3 years.
	Pocket dosimeter calibrations.	2 years. <u>3 years.</u>
	Film badge, OSL device, or TLD reports.	Until disposal is authorized by the agency. <u>Until the agency terminates the license.</u>
	Alarming ratemeter calibrations.	2 years. <u>3 years.</u>
	Alarming ratemeter functions.	2 years. <u>3 years.</u>
	<u>Estimates of overexposures</u>	<u>Until the agency terminates the license.</u>
45.1(19)	Current operating and emergency procedures.	Until the license is terminated.
	Superseded material.	3 years after change.
40.81(1)	Internal audit program.	3 years.
45.1(11)	Radiographer audits.	3 years.
45.2(5) and 45.3(7)	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure.
45.1(16)	Records at temporary job sites.	During temporary job site operations.
45.2(6) and 45.3(8)	Annual evaluation of enclosed X-ray systems.	2 years.
45.3(5)	Leak tests	3 years.
45.1(9)	Tests of Chapter 45 high radiation control devices and alarm systems.	Until disposal is authorized by the agency.

45.2(6) Evaluation of certified cabinet
X-ray systems. 2 years.

ITEM 120. Amend subrule **46.5(1)**, paragraph "c," subparagraph (2) as follows:

(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 as shown in Appendix 3.~~

ITEM 121. Amend subrule **46.5(1)**, paragraph "c," by adopting **new** subparagraph (6) as follows:

(6) The items in 46.5(1)"c"(1), (2) and (3) shall be posted in each tanning room.

ITEM 122. Amend subrule **46.5(8)** by adopting **new** paragraph "e" as follows:

e. A tanning facility operator shall instruct the consumer in the proper utilization of the protective eyewear required by this subrule.

ITEM 123. Amend subrule **46.6(3)** as follows:

46.6(3) If the ~~director~~ agency finds that a person has violated, or is violating or threatening to violate, this chapter and that the violation creates an immediate threat to the health and safety of the public, the ~~director~~ agency may petition the district court for a temporary restraining order to restrain the violation or threat of violation.

If a person has violated, or is violating or threatening to violate, this chapter, the agency may petition the district court for an injunction to prohibit the person from continuing the violation or threat of violation.

ITEM 124. Amend subrule **46.6(5)**, paragraph "c," as follows:

c. In cases where the permit holder fails to comply with conditions of the written notice, the ~~department~~ agency shall send a regulatory letter, via certified mail, advising the permit holder that unless action is taken within five days of receipt, the case shall be turned over to the appropriate state/city/county attorney for court action.

ITEM 125. Amend 641—Chapter 46 by adopting **new** Appendix 3 as follows:

Appendix 3

POTENTIAL NEGATIVE HEALTH EFFECTS RELATED TO ULTRAVIOLET EXPOSURE

1. Increased risk of skin cancer later in life.
2. Increased risk of skin thickening and premature aging.
3. Possibility of burning or rash, especially if using any of the potential photosensitizing drugs and agents. The consumer should consult a physician before using a tanning device if using medications, if there is a history of skin problems or if the consumer is especially sensitive to sunlight.
4. Increased risk of eye damage unless proper eyewear is worn.

Mary Mincer Hansen, RN, PhD., Director
Department of Public Health

Date