

PUBLIC HEALTH DEPARTMENT [641]

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Notice of Intended Action

Pursuant to the authority of Iowa Code section 136C.3, the Iowa 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 Machines 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 itemizes the proposed changes.

Items 1, 7, 10, 16, 44, and 48 amend the rules to reflect current federal codes.

Item 2 changes a definition to include all sources of radiation possibly administered to humans. It adds a definition inadvertently deleted when the definition of misadministration was changed. It adds two definitions inadvertently deleted in a past rule change.

Item 3 changes the fee structure to allow deviation from the federal fee schedule. The agency can adjust fees based on the actual cost.

Item 4, 5, and 41 add or increase late fees to deter late submissions and help decrease staff workload. The second paragraph is also updated to cover all areas in the agency's radiation rules where a fee is charged.

Item 6 is added to help recover costs involved in training staff and monitoring shipments.

Item 8 and 9 moves wording from out-of-state requirements to in-state requirements since the requirement is for in-state licensees only.

Items 11, 12, 13, 14, 15, 22, and 23 correct inaccurate references.

Item 17 rescinds a definition that was moved to Chapter 38.

Items 18 and 39 change wording to indicate that shielding plans meet certain standards. The agency does not approve shielding plans.

Item 19 places a requirement in written procedures for the operator to follow good health protection practices. Inspections showed that even though the facility met the protective barrier requirement, the operator was not following good health protection practices.

Item 20 restricts moveable x-ray systems from being moved from a shielded room to a non-shielded room and allowing unnecessary radiation exposure.

Item 21 exempts veterinary systems from meeting requirements that are not necessary for veterinary systems.

Item 24, 25, 26, and 27 amend rules to include items inadvertently omitted when the definition of misadministration was changed. The definition of "reportable medical event" was added in item 2.

Item 28 changes the requirement to include all settings frequently used so that more accurate checks are preformed.

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Item 29 and 30 allow use of sources not specifically listed further in the rule. This means the agency does not have to amend the rule for every new source marketed.

Item 31 adds training requirements for a new areas of use for authorized users of radioactive material.

Items 32, 33, 34, 35, 36, 37, and 38 change wording to clarify the difference between mammography units used for diagnostic purposes and biopsy units which are for tissue removal.

Item 40 changes the way we assign approval to limited radiographers. This should make the designation easier to understand. It also prohibits views normally used in mobile chest radiography since many limited radiographers are now being employed by hospitals where mobile chest units are common. Mobile chest radiography is considered beyond the scope of practice for limited radiographers.

The definitions involving simulation radiography have been changed to prohibit simulation therapists from using isotopes because they are not trained to use them.

Item 42 allows a nuclear pharmacist to oversee certain training of nuclear medicine technologists. This is standard practice in training institutions.

Item 43 changes the definition to include x-ray systems since both sealed source and x-ray systems are used for industrial radiography and regulated in these rules.

Items 45 and 46 allow an individual approved for industrial radiography by another certifying entity to work in Iowa under reciprocity. Since many individuals work in Iowa for companies not based in Iowa, this ensures that they meet the same qualifications as individuals certified by Iowa.

Item 47 deletes duplicate wording that is included in the definition.

Item 49 adds a fee for regaining a suspended or revoked permit in order to recover fees incurred in the suspension or revocation process. Some individuals allow suspension or revocation in order to avoid additional penalties, then reinstate at a later date.

Item 50 allows for the counties who contract to perform tanning inspections to regain costs incurred in order to get facilities to correct violations in a timely manner.

Item 51 is changed to prevent two individuals from being in the tanning room at the same time. When two individuals are in the room at the same time, the operator does not have control over the exposure times of the individuals.

Item 52 prohibits "unlimited" tanning so that the facility must meet the exposure schedules recommended by the manufacturer.

These rules are subject to waiver pursuant to the Department's exemption provision contained at 641—38.3(136C). For this reason, the Department has not provided a specific provision for waiver of these particular rules.

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on February 27, 2001. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa 50309; fax: (515)725-0318; or E-mail: dflater@idph.state.is.ua.

A public hearing will be held on February 27, 2001, at 8:30 a.m., Conference Room, Iowa Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

Any person who plans to attend a public hearing and has special requirements such as hearing or mobility impairments should contact the Department of Public Health to advise of specific needs.

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

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 10, 2000~~ May 9, 2001.

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

Amend the following definition:

"Healing arts screening" means the testing of human beings using ~~X-ray machines~~ radiation for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)"a"(7) or listed as an authorized user on a Iowa, U.S. Nuclear Regulatory Commission, or agreement state radioactive materials license.

Add the following new definitions:

"Reportable medical event" means the administration of radioactive material for diagnostic medical use that results in the patient or human research subject (1) receiving greater or less than twenty percent of a prescribed dose; (2) receiving a dose intended for another individual; or (3) receiving a dose that was not prescribed by an authorized user.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material, or A_2 , for normal form radioactive material, where A_1 and A_2 are given in, or may be determined by procedures described in Chapter 39, Appendix E.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

ITEM 3. Amend subparagraph **38.8(2)"a"(1)** as follows:

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa ~~are identical to those shall not exceed those specified in 10 CFR 170.31 entitled "Schedule of Fees for Materials Licenses and Other Regulatory Services."~~

ITEM 4. Amend subrule 38.8(6) by adopting new paragraph as follows:

d. Continuing education late fee. Any individual who will not complete the required continuing education before the continuing education due date and wishes to submit a plan of correction as set forth in 641—paragraph 42.2(3)"g" paragraph (2), shall submit a fee of \$25 along with the written plan of correction.

ITEM 5. Amend subrule **38.8(7)** as follows:

a. ~~\$15~~ \$25 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. \$25 for each month for failure to pay ~~annual radiation machine registration or diagnostic radiation operator fee~~ any fee administered by this agency starting the first day

~~of the month after the expiration of the facility's registration or operator's permit to practice~~ 30 days after the due date of the original notice. This fee is added to the unpaid annual fee.

ITEM 6. Amend subrule 38.8 by adopting new numbered subrule **38.8(12)** as follows:
38.8(12) Radioactive waste transportation.

a. All shippers of waste containing radioactive materials, transporting waste across Iowa, shall pay the following fee(s) unless the agency is able to obtain appropriate funding from another source (ie: federal agency).

1. \$1750 per truck 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 per mile for every mile over 250 miles for the first truck in each shipment.

2. \$250 per truck for transport of low-level radioactive waste.

3. \$1250 for the first cask and \$100 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.

4. \$250 for the first railcar and \$50 for each additional railcar in the train for transport of low-level radioactive waste.

b. All fees must be received by the agency prior to shipment. The agency will provide each shipper with a "Certificate of Payment of Fees." The certificate must be with the shipment when it enters Iowa and available for inspection by the agency or a representative of the Motor Carrier Safety Division of the Iowa Department of Transportation.

ITEM 7. 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 10, 2000~~ May 9, 2001.

ITEM 8. Amend subparagraph **39.4(90)"a"(1)** as follows:

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, ~~which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.~~

ITEM 9. Amend subrule 39.4(1) by amending paragraph "a" and adding new paragraph "b":

~~39.4(1)~~39.4(1) Additional requirements.

a. In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; and licensees engaged in land disposal or radioactive material are subject to the requirements of 641—Chapter 40.

b. An Iowa radioactive materials license requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored. The office must have at least one full-time employee and a telephone.

ITEM 10. 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 10, 2000~~May 9, 2001.~~

ITEM 11. Amend subrule 40.26(3), paragraph "a" as follows:

a. ~~Demonstration of the need for and the expected duration of operations in excess of the limit in 40.13(1)~~40.26(1); and

ITEM 12. Amend subrule 40.65(1) as follows:

40.65(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 641—subrule 39.5(2) and appendix E of 641—Chapter 39, shall make arrangements to receive:

ITEM 13. Amend paragraph 40.65(1)"b" as follows:

b. Monitor the external surfaces of a labeled³ package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, ~~as defined in 641—subrule 39.5(2) and Appendix E to 641—Chapter 39; and~~

ITEM 14. Amend paragraph 40.65(4)"b" as follows:

b. External radiation levels exceed the limits of ~~641—paragraph 39.5(15)"i" and 641—paragraph 39.5(15)"j."~~10 CFR 71.47 as set forth in 641—39.5.

ITEM 15. Amend subrule 40.111(1), paragraph "f" as follows:

f. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to ~~641—40.113(136C).~~641—40.112(136C).

ITEM 16. Amend subrule 41.1(1) as follows:

41.1(1) Scope. This rule established requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provision of this rule are in addition to, and not in substitution for, any other applicable provisions of these rules. The provisions of Chapter 41 are in addition

to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 10, 2000~~ May 9, 2001.

ITEM 17. Amend subrule **41.1(2)** by rescinding the following definition:

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)"a"(7).

ITEM 18. Amend subparagraph **41.1(3)"d"(1)**, as follows:

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and ~~approval~~ verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

ITEM 19. Amend subparagraph **41.1(6)"b"(2)**, third paragraph, as follows:

Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure.

ITEM 20. Amend subrule **41.1(6)** by adopting new paragraph "k" as follows:

k. Systems used in a clinical (non-surgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3)"d."

ITEM 21. Amend subrule **41.1(10)"c"** as follows:

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1 except for 641—41.1(3) and 41.1(10).

ITEM 22. Amend subrule **41.2(5)"a"** as follows:

a. A licensee shall provide to the agency a copy of the board certification, the NRC or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as ~~an~~ a visiting authorized user or an ~~a visiting authorized nuclear pharmacist pursuant to 41.2(4)"b"(1) to 41.2(4)"b"(4).~~

ITEM 23. Amend paragraph **41.2(9)"b"(2)**, subparagraph 2. as follows:

2. Review, ~~pursuant to 41.2(4)"b"(1) to 41.2(4)"b"(4),~~ on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

ITEM 24. Amend subrule **41.2(14)** and first sentence of paragraph "a" as follows:

41.2(14) Records and reports of misadministrations, reportable medical events, and written directives.

a. When a misadministration ~~involves any therapy procedure~~ occurs, the licensee shall notify the agency by telephone.

ITEM 25. Amend subparagraph **41.2(14)"b"(1)**, the first sentence as follows:

(1)The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration and 30 days after discovery of a reportable medical event.

ITEM 26. Rescind subparagraph **41.2(14)"c."**

ITEM 27. Amend paragraph **41.2(14)"d,"** the first sentence as follows:

d. Each licensee shall retain a record of each misadministration for ten years and each reportable medical event for three years.

ITEM 28. Amend subparagraph **41.2(17)"b"(1)** as follows:

(1)Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used ~~settings~~ settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

ITEM 29. Amend subrule **41.2(41)** as follows:

41.2(41) Use of sealed sources for diagnosis. A licensee shall use the following sealed sources or any sealed source for which the Food and Drug Administration has a "Premarket Approval Application (PMA)" for diagnostic uses in accordance with the manufacturer's radiation safety and handling instructions:

ITEM 30. Amend subrule **41.2(43)** as follows:

41.2(43) Use of sources for brachytherapy. A licensee shall use the following sources or any sealed source for which the Food and Drug Administration has a "Premarket Approval Application (PMA)" for therapeutic uses in accordance with the manufacturer's radiation safety and handling instructions:

ITEM 31. Amend subparagraph **41.2(69)"b"(2)**, paragraph 5. and add new subparagraph 6. as follows:

5. Use of strontium-89 or samarium-153 for relief of pain in metastatic disease in three individuals; ~~or~~

6. Use of iodine-131 radiolabeled monoclonal antibody for treatment of non-Hodgkin's Lymphoma in three patients; or

ITEM 32. Amend rule **641—41.7(136C)** as follows:

641—41.7(136C) X-ray machines used for ~~mammographically~~ stereotactically guided breast biopsy.

41.7(1)Definitions. In addition to the definitions provided in rule 41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)"a" or 41.7(3)"c") are working together in consultation and in performing mammographicallystereotactically guided breast biopsies with a common goal of the patient's benefit.

"Mammographicallystereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

ITEM 33. Amend subrule 41.7(2) as follows:

41.7(2)Registration and application standards and requirements.

a. Each radiation machine used to perform mammographicallystereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform mammographicallystereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The mammographicallystereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform mammographicallystereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire mammographicallystereotactically guided breast biopsy system is evaluated annually by a radiation physicist who meets the requirements of this rule.

ITEM 34. Amend subrule 41.7(3) as follows:

41.7(3)Physicians. Physicians must be qualified according to the setting and their role in performing mammographicallystereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)"b".

2. Shall have performed at least 12 mammographicallystereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hand-on imagestereotactically guided breast biopsies under a physician who is qualified under 41.6(3)"b" and has performed at least 24 mammographicallystereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME in imagestereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in "2" above and be experienced in recommendations for biopsy and lesion identification at time of biopsy.

5. Shall be responsible for oversight of all quality control and quality assurance activities.

6. Shall be responsible for the supervision of the radiologic technologist and the medical physicist.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographicallystereotactically guided breast biopsies per year or requalify as specified above in 41.7(3)"a"(1).

2. Obtain at least three hours of Category 1 CME in mammographicallystereotactically guided breast biopsy every three years.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must have at least three hours of Category 1 CME in mammographicallystereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

2. Must have performed at least 12 mammographicallystereotactically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on mammographicallystereotactically guided breast biopsy procedures under a physician who is both qualified to interpret mammography according to 41.6(3)"b" and has performed at least 24 mammographicallystereotactically guided breast biopsies.

3. Shall be responsible for ~~postbiopsy~~ post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 mammographicallystereotactically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME in mammographicallystereotactically guided breast biopsy every three years.

c. Requirements for a radiologist performing mammographicallystereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)"b".

2. Initially, must have at least three hours of Category 1 CME in mammographicallystereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 mammographicallystereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on mammographicallystereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)"b" and has performed at least 24 mammographicallystereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

8. Must be responsible for the oversight of all quality control.

9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

10. Must be responsible for postbiopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years which includes postbiopsy management of the patient.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)"c") performing mammographically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must have evaluated at least 480~~240~~ mammograms per year in the prior two years in consultation with a physician who is qualified according to 41.6(3)"b".

2. Initially, must have at least 15 hours of Category 1 CME in mammographically guided breast imaging and biopsy or three years' experience having performed at least 36 imagestereotactically guided breast biopsies.

3. Must have four hours of Category 1 CME in medical radiation physics.

4. Must have performed at least 12 mammographically guided breast biopsies prior to the effective date of these rules, or at least 3 hands-on mammographically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)"b" and has performed at least 24 imagestereotactically guided breast biopsies.

5. Must be responsible for patient selection.

6. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies, cancers found, benign lesions, biopsies needing repeat and complications).

7. Must be responsible for oversight of all quality control.

8. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

9. Must be responsible for postbiopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480~~240~~ mammograms per year in consultation with a physician who is qualified according to 41.6(3)"b".

2. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

3. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

ITEM 35. Amend subrule 41.7(4) as follows:

41.7(4)Medical physicist.

a. Must be qualified according to 41.6(3)"c."

b. Must meet the following initial requirements:

(1) Prior to July 1, 1998, have performed three hands-on mammographically guided breast biopsy system physics surveys; or one

hands-on mammographicallystereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)"a" and 41.7(4)"b."

(2) On or after July 1, 1998, have one hands-on imagestereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified to perform mammographicallystereotactically guided breast biopsy system physics surveys. Have at least one mammographicallystereotactically guided breast biopsy system physics survey per year after the initial qualifications are met; and three hours of continuing education in mammographicallystereotactically guided breast biopsy system physics every three years after the initial qualifications are met.

ITEM 36. Amend subrule 41.7(5) as follows:

41.7(5) Radiologic technologist.

a. Must be qualified according to 41.6(3)"d."

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a qualified physician or technologist.

(2) Three hours of continuing education in mammographicallystereotactically guided breast biopsy.

c. Thereafter, an average of at least 12 mammographicallystereotactically guided breast biopsies per year after initial qualifications are met.

d. Three hours of continuing education in mammographicallystereotactically guided breast biopsy every 3 years after initial qualifications are met.

ITEM 37. Amend subrule 41.7(7) as follows:

41.7(7) Quality assurance program.

a. The facility shall have an equipment quality assurance program specific to imagestereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

ITEM 38. Amend subrule 41.7(8) as follows:

41.7(8) Equipment standards.

a. Be specifically designed for mammographicallystereotactically guided breast biopsy.

ITEM 39. Amend **641—Chapter 41**, Appendix A, the first paragraph, as follows:

In order for the agency to provide an evaluation, ~~technical advice, and official approval~~ and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

ITEM 40. Amend subrule **42.1(2)**, definitions of "Chest," "Diagnostic radiographer," "Simulation radiography," and "Simulation therapist," as follows:

"Chest" is defined as lung fields including the cardiac shadow, as taught in the approved limited radiography curriculum. Radiography of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum for diagnostic evaluation of these body structures or chest radiography using anything other than a vertical cassette holder is not allowed under this body part classification for limited diagnostic radiographers. Limited radiographers

already approved in "chest" radiography may perform oblique, apical lordotic, and decubitus chest views under this definition upon completion of additional training approved by this agency.

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

1. "General diagnostic radiographer" applies X-radiation to any part of the human body.

2. "Limited diagnostic radiographer" applies X-radiation to not more than ~~two body parts~~. Chest and extremity radiographic examinations are considered as one body part. three of the following body parts: chest, extremities (upper and lower), spine, or sinus.

"Simulation radiography" means the science and art of applying ~~X-radiation~~radiation to human beings for the purpose of localizing treatment fields ~~and isotopes~~ and for treatment planning.

"Simulation therapist" means an individual, other than a physician, who applies ~~X-radiation~~radiation to human beings for the purpose of localizing treatment fields ~~and isotopes~~ and for treatment planning.

ITEM 41. Amend subrule 42.2(3)"g", paragraph (2), as follows:

(2)Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours and the fee required in 641—paragraph 38.8(6)"d" shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

ITEM 42. Amend subrule 42.4(4), paragraph "a" as follows:

a. Students enrolled in and participating in an approved program or approved course of study for nuclear medicine technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radioactive material to a human being while under the supervision of a licensed physician who appears as an authorized user on an Iowa, agreement state, or NRC radioactive materials license. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa or NRC radioactive materials license. Quality assurance and quality control experience may be directly supervised by a nuclear pharmacist who appears as an authorized user on an Iowa, U.S. Nuclear Regulatory Commission, or agreement state radioactive materials license.

ITEM 43. Amend subrule 45.1(2) by amending the following definition:

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of

making a radiographic exposure (e.g., camera), or any other industrial system whereby a permanent or semi-permanent image is recorded on an image receptor by action of ionizing radiation.

ITEM 44. Amend subrule 45.1(1) as follows:

45.1(1) Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapter 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1999~~ May 9, 2001.

ITEM 45. Amend subrule **45.1(10)"g,"** subparagraph (1) as follows:

(1) I.D. Card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10)"b" and the examination prescribed in 45.1(10)"f"(2) or an equivalent examination. ~~Certification by a certifying entity in accordance with 10 CFR 34.43(a)(1) meets the examination requirements of 45.1(10)"f"(2) but not the requirements of 45.1(10)"b"(1).~~

ITEM 46. Amend subrule 45.1(10) by adopting new paragraph as follows:

j. Reciprocity.

(1) Reciprocal recognition by the agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category and class issued by a certifying entity as defined in 45.1(2).

2. The requirements and procedures of the certifying entity issuing the certification require the same or comparable certification standards as those required by 45.10(1)"a" through "e;" and

3. The individual submits a legible copy of the certification to the agency prior to entry into Iowa.

(2) Enforcement actions with the agency, another agreement state, or the U.S. Nuclear Regulatory Commission, or any sanctions by an independent certifying entity may be considered when reviewing a request for reciprocal recognition from a licensee, registrant, or certified radiographer.

(3) Certified radiographers who are granted reciprocity by the agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 45.1(10)"b."

ITEM 47. Amend paragraph **45.2(6)"b"** as follows:

b. Certified and certifiable cabinet X-ray systems ~~designed to exclude individuals from the interior of the cabinet~~ are exempt from the requirements of this chapter except that:

ITEM 48. Amend rule **641—46.1(136D)**, first unnumbered paragraph, as follows:

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 10, 2000~~ January 1, 2001.

ITEM 49. Amend subrule 46.4(6) by adopting the following new paragraph:

d. Once a permit to operate has been suspended or revoked, it may be reinstated upon receipt of a fee of \$50 and completion of all other agency requirements. This fee is in addition to other applicable fees.

ITEM 50. Amend subrule 46.4(7), paragraph "b," by adopting the following new subparagraph:

(4) A penalty fee of \$25 per facility may be assessed for the following:

1. Failure to respond to a notice of violation within 30 days of the date of the inspection.
2. Failure to correct violations cited during the inspection.

ITEM 51. Amend subrule 46.5(9), paragraph "j," as follows:

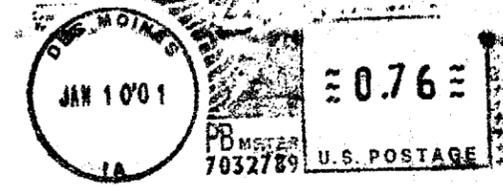
j. When a tanning device is being used, no other person shall be allowed to remain in the tanning device area ~~unless protective eyewear is worn~~.

ITEM 52. Amend subrule 46.5(9), by adopting new paragraph "k" as follows:

k. No person or facility shall advertise or promote tanning packages labeled as "unlimited" unless tanning frequency limits set by the manufacturer are included in advertisements.

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RADIATION



FROM: IOWA DEPT. OF PUBLIC HEALTH
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