

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 136B.4, 136C.3 and 136D.7, 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 44, "Minimum Requirements for Radon Mitigation," and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following paragraphs itemize the proposed changes:

Items 1, 3, 9, and 13 amend the rules to reflect current federal regulations.

Item 2 adds an application fee for industrial radiographers. Fees are used to meet the costs of processing the application and issuing the permit card.

Item 4 adds a category for service provider registration. This category is added to clarify the categories of those required to register.

Item 5 corrects the language previously corrected elsewhere by changing the two-working-day period to a three-working-day period.

Item 6 rescinds a requirement for a permanent office in Iowa for registrants and licensees.

Item 7 adds an omitted reference.

Item 8 adds a new paragraph in order to meet the Nuclear Regulatory Commission compatibility requirements.

Items 10 and 12 amend language involving nationally tracked sources. Items 10 and 12 amend language to meet Nuclear Regulatory Commission compatibility requirements.

Item 11 corrects the address for obtaining forms.

Items 14 and 46 add clarifying language to require operators to have a current permit to practice. The permit is required by Chapter 42.

Items 16 to 21, 23 to 25, and 27 to 44 correct references to meet Nuclear Regulatory Commission compatibility requirements.

Item 22 amends the title of the studies. This change corrects language previously corrected elsewhere in Chapter 41 in order to meet the Nuclear Regulatory Commission compatibility requirements.

Item 26 rescinds a paragraph to meet Nuclear Regulatory Commission compatibility requirements.

Item 45 corrects the name of the college to meet Nuclear Regulatory Commission compatibility requirements.

Item 47 amends definitions and adds new definitions to meet FDA standards for digital mammography.

Item 48 adds language to include reinstatement for mammography certification.

Items 49 and 50 amend language to include suspension, revocation and denial of mammography certification.

Items 51 and 52 amend and adopt new language regarding the accreditation process for mammography facilities.

Item 53 adds new language for computers used for mammography interpretation.

Items 54 to 61 add and correct language for training and continuing education for physicians, physicists, and technologists involved with mammography.

Items 62 to 64 adopt new language for clarification of mammography requirements.

Item 65 changes the time requirements for retaining mammography films.

Items 66 to 68 add language for digital mammography or to specify film-screen mammography or digital mammography.

Item 69 adds language requiring the reviewing physician to sign the required audits.

Item 70 corrects language for base plus fog density tests.

Item 71 removes language allowing a different requirement before an effective date of October 28, 2002.

Item 72 adds a new paragraph for digital mammography units.

Items 73 and 75 add new language for digital mammography units.

Item 74 clarifies language for mammography equipment evaluations.

Item 76 adopts new definitions necessary for clarification of terms in mammography.

Item 77 clarifies the type of physicist needed for the mammography evaluations.

Item 78 changes the word “withdrawal” to “suspension or revocation” for clarification of mammography disciplinary actions.

Item 79 adds a statement requiring inspections after revocation of mammography authorization.

Items 80, 84, and 86 correct references and remove a quality control responsibility for mammography physicians.

Items 81, 83, 85, and 87 add language for physicians performing stereotactically guided breast biopsies. The wording adds requirements for physicians who do not maintain the experience or education requirements. Items 81 and 83 also adopt new language to require physicians to have an Iowa medical license.

Item 82 adopts new language to require physicians to be responsible for supervision of radiologic technologists during procedures.

Item 88 rearranges wording for clarification.

Item 89 adds language for requalification in mammography.

Item 90 adds language to restrict hours to be earned for continuing education in mammography.

Item 91 amends wording for clarification and adds wording for requalification in mammography.

Item 92 adds language for additional identifiers for mammography records and corrects the type of physicist allowed.

Item 93 changes “radiation physicist” to “medical physicist” to clarify the qualifications of the individual.

Item 94 adds a new paragraph for responsibilities for a supervising stereotactic biopsy physician.

Items 95 to 97 expand language that specifies the requirements for mammography equipment.

Item 98 adds wording to clarify the qualifications of a medical physicist in mammography.

Item 99 adds wording to include all types of individuals covered under Chapter 42.

Item 100 changes the term “podiatry assistant” to “podiatric radiographer.” The new term more accurately reflects the position. The amendment also clarifies definitions by specifying “advanced” CPR and by adding language to differentiate between indirect and direct supervision and adds two new definitions for “directly related” and “formally educated” for clarification.

Item 101 adds language to accurately reflect the supervision requirements for the different modalities.

Items 102, 103, 106, 109, 110, and 115 to 118 change the term “podiatry assistant” to “podiatric radiographer.” The new term more accurately reflects the position.

Item 104 changes wording to make the language more uniform.

Item 105 adds the word “current” to clarify the distinction between “expired” and “current.”

Items 107 and 111 add language for clarity.

Item 108 corrects a misspelled word.

Item 109 removes language requiring penalty hours for late submission of continuing education. This action follows guidelines of the national certification body.

Item 112 adds language to refer the various modalities to the proper area of the rules for training requirements. The amendment explains the requirements to be submitted for approval of a training program and includes requirements for instructors.

Item 113 changes the word “trained” to “educated” to better define the requirements for a supervising individual.

Item 114 removes a provision allowing temporary certification. The requirement for examination before certification is now uniform with other modalities.

Item 119 adds wording to clarify the fees required for radon mitigation installations.

Item 120 adds wording to require posting of instructions in tanning rooms to make the requirement uniform with other parts of Chapter 46.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on April 9, 2008, as ARC 6711B. A public hearing was held on April 29, 2008. No individuals attended the

hearing. Four sets of written comments were received and reviewed. No changes were made from the Notice of Intended Action.

The State Board of health adopted these amendments on May 14, 2008.

These amendments will become effective July 23, 2008.

These amendments are intended to implement Iowa Code chapters 136B, 136C, and 136D.

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 ~~April 30, 2007~~ July 9, 2008.

ITEM 2. Amend subrule **38.8(3)** by adopting new paragraph “c” as follows:

c. A nonrefundable fee of \$75 shall be submitted with each application, not associated with an agency-administered industrial radiography examination, for a trainee or trainer card issued to a radiographer’s assistant or an industrial radiographer.

ITEM 3. 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 ~~April 30, 2007~~ July 9, 2008.

ITEM 4. Amend subrule **39.3(3)**, paragraph “d,” by adopting new subparagraph (5) as follows:

(5) Calibration and compliance surveys of external beam radiation therapy units.

ITEM 5. Amend subrule **39.3(10)**, paragraph “b,” as follows:

b. If, for a specific case, the ~~two three~~-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

ITEM 6. Amend subrule **39.4(20)** by rescinding paragraph “c” and relettering paragraph “d” as “c.”

ITEM 7. Amend subrule **39.4(29)**, paragraph “1,” introductory paragraph, as follows:

1. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration or reference source or for the uses listed in 641—subrules 41.2(41), ~~and 41.2(43)~~, and 41.2(49) will be approved if:

ITEM 8. Amend subrule **39.4(33)**, paragraph “g,” subparagraph (4), by renumbering numbered paragraph “6” as “7” and adopting a new numbered paragraph “6” as follows:

6. A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

6 7. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based on the criteria in paragraph “i” of this subrule.

ITEM 9. 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 3, 2006~~ July 9, 2008.

ITEM 10. Amend subrule **40.99(8)**, introductory paragraph, as follows:

40.99(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by ~~November 15, 2007~~ January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by ~~November 30, 2007~~ January 31, 2009. This information may be submitted by using any of the methods identified in subrule 40.99(6). The initial inventory report must include the following information:

ITEM 11. Amend ~~641—Chapter 40, Appendix D~~, section I (c), second paragraph, as follows:

NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, by writing or calling the Office of Information Resources Management Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0111, telephone (301) 415-7232 5877 or by visiting the NRC’s Web site at [http:// www.nrc.gov](http://www.nrc.gov) and selecting forms from the index found on the home page.

ITEM 12. Amend ~~641—Chapter 40, Appendix H~~, as follows:

CHAPTER 40
APPENDIX H
NATIONALLY TRACKED SOURCE THRESHOLDS

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16.0
Americium-241/Be	60	1,600	0.6	16.0
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	15.0 14.0
Cesium-137	100	2,700	1.0	27.0
Gadolinium-153	1,000	27,000	10.0	270.0
Iridium-192	80	2,200	0.8	22.0
Plutonium-238	60	1,600	0.6	16.0
Plutonium-239/Be	60	1,600	0.6	16.0
Polonium-210	60	1,600	0.6	16.0
Promethium-147	40,000	1,100,000	400.0	11,000.0
Radium-226	40	1,100	0.4	11.0
Selenium-75	200	5,400	2.0	54.0
Strontium-90	1,000	27,000	10.0	270.0
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200.0	5,400.0
Ytterbium-169	300	8,100	3.0	81.0

ITEM 13. 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 ~~April 30, 2007~~ July 9, 2008.

ITEM 14. Amend subrule **41.1(3)**, paragraph “**a**,” subparagraph (2), numbered paragraph “**1**,” as follows:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42 as applicable, and have a current permit to practice in diagnostic radiography. The individual’s permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

ITEM 15. Amend subrule **41.2(11)**, paragraph “**a**,” subparagraph (5), as follows:

(5) Require that only those individuals ~~specifically trained~~ certified and issued a current permit to practice 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 (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, 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 16. Amend subrule **41.2(31)**, paragraph “**b**,” subparagraph (2), as follows:

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or before May 3, 2006, who meets the requirements of 10 CFR ~~35.920~~ 290; or

ITEM 17. Amend subrule **41.2(33)**, paragraph “**b**,” as follows:

b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69), or an individual under the supervision of either as specified in 41.2(11);

ITEM 18. Amend subrule 41.2(67), introductory paragraph, as follows:

41.2(67) Training for uptake, dilution, and excretion studies. Except as provided in 41.2(75) ~~and 41.2(76)~~, the licensee

shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

ITEM 19. Amend subrule **41.2(67)**, paragraph “**b**,” as follows:

b. Is an authorized user under 41.2(68) or 41.2(69), or before May 3, 2006, meets the requirements in ~~10 CFR 35.910, 35.920, or 35.930~~ 10 CFR 35.190, 35.290, or 35.390, or meets equivalent agreement state requirements; or

ITEM 20. Amend subrule **41.2(67)**, paragraph “**c**,” subparagraph (1), numbered paragraph “**2**,” introductory paragraph, as follows:

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), or 41.2(69), or before May 3, 2006, the requirements in ~~10 CFR 35.910, 35.920, or 35.930~~ 10 CFR 35.190, 35.290, or 35.390, or equivalent agreement state requirements, involving:

ITEM 21. Amend subrule **41.2(67)**, paragraph “**c**,” subparagraph (2), as follows:

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), or 41.2(69), or before May 3, 2006, the requirements in ~~10 CFR 35.910, 35.920, or 35.930~~ 10 CFR 35.190, 35.290, or 35.390, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(67)“a”(1) or 41.2(67)“c”(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31).

ITEM 22. Amend subrule **41.2(68)**, paragraph “**a**,” subparagraph (1), as follows:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for ~~uptake, dilution, and excretion~~ imaging and localization studies that include the topics listed in 41.2(68)“c”(1)“1” and “2”; and

ITEM 23. Amend subrule **41.2(68)**, paragraph “**b**,” as follows:

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68)“c”(1)“2,” seventh bulleted paragraph, or before May 3, 2006, meets the requirements in 10 CFR ~~35.920~~ 35.290, or equivalent agreement state requirements; or

ITEM 24. Amend subrule **41.2(68)**, paragraph “**c**,” subparagraph (1), numbered paragraph “**2**,” introductory paragraph, as follows:

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68) or 41.2(68)“c”(1)“2,” seventh bulleted paragraph, and 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR ~~35.920~~ 35.290, or equivalent agreement state requirements, involving:

ITEM 25. Amend subrule **41.2(68)**, paragraph “**c**,” subparagraph (2), as follows:

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68) or 41.2(69) and 41.2(68)“c”(1)“2,” seventh bulleted paragraph, or before May 3, 2006, meets the requirements in 10 CFR ~~35.920~~ 35.290, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(68)“a”(1) or 41.2(68)“c”(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

ITEM 26. Rescind subrule **41.2(68)**, paragraph “**d**.”

ITEM 27. Amend subrule **41.2(69)**, paragraph “**b**,” subparagraph (1), numbered paragraph “**2**,” introductory paragraph, as follows:

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b,” or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390(b) must also have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)“b”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

ITEM 28. Amend subrule **41.2(69)**, paragraph “**b**,” subparagraph (2), as follows:

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)“a”(1) and 41.2(69)“b”(1)“2,” seventh bulleted paragraph, or 41.2(69)“b”(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, or equivalent agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)“b,” or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)“b”(1)“2,” seventh bulleted paragraph) as the individual requesting authorized user status.

ITEM 29. Amend subrule **41.2(70)**, paragraph “**b**,” subparagraph (1), numbered paragraph “**2**,” introductory paragraph, as follows:

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940~~ 35.490, or equivalent agreement state requirements at a medical institution, involving:

ITEM 30. Amend subrule **41.2(70)**, paragraph “**b**,” subparagraphs (2) and (3), as follows:

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940~~ 35.490, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70)“b”(1)“2”; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940~~ 35.490, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70)“a”(1) or 41.2(70)“b”(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses in 41.2(43).

ITEM 31. Amend subrule **41.2(71)**, paragraph “**a**,” as follows:

a. Is an authorized user under 41.2(70), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940~~ 35.490 or ~~35.941~~ 35.491, or equivalent agreement state requirements; or

ITEM 32. Amend subrule **41.2(71)**, paragraph “**b**,” subparagraph (3), as follows:

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(71), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940~~ 35.490 or ~~35.941~~ 35.491, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71)“a” and “b” and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

ITEM 33. Amend subrule **41.2(73)**, paragraph “**b**,” subparagraph (1), numbered paragraph “**2**,” introductory paragraph, as follows:

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR ~~35.960~~ 35.690, or equivalent agreement state requirements at a medical institution, involving:

ITEM 34. Amend subrule **41.2(73)**, paragraph “**b**,” subparagraphs (2) and (3), as follows:

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR ~~35.960~~ 35.690, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)“b”(1)“2”; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)“a”(1) or 41.2(73)“b”(1) and (2), and 41.2(73)“c,” and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73), or before May 3, 2006, the requirements in 10 CFR ~~35.960~~ 35.690, or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

ITEM 35. Amend subrule **41.2(74)**, paragraph “**b**,” subparagraph (2), as follows:

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74)“a”(1) and (2) and 41.2(74)“c” or 41.2(74)“b”(1) and 41.2(74)“c,” and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74), or before May 3, 2006, the requirements in 10 CFR ~~35.961~~ 35.51, or equivalent agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

ITEM 36. Amend subrule **41.2(81)**, paragraph “**b**,” as follows:

b. Is an authorized user under 41.2(69)“a” or “b” for uses in the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, or before May 3, 2006, who meets the requirements in 10 CFR ~~35.930, 35.932, or 35.934~~ 35.390, 35.392, or 35.394, or meets equivalent agreement state requirements; or

ITEM 37. Amend subrule **41.2(81)**, paragraph “**c**,” subparagraph (2), introductory paragraph, as follows:

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b,” or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930, 35.932, or 35.934~~ 35.390, 35.392, or 35.394, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131. The work experience must involve:

ITEM 38. Amend subrule **41.2(81)**, paragraph “**c**,” subparagraph (3), as follows:

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)“c”(1) and (2), and has achieved a level of competency sufficient to function independently as an

authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(81), or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930, 35.932, or 35.934~~ 35.390, 35.392, or 35.394, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)“b” must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131.

ITEM 39. Amend subrule **41.2(82)**, paragraph “**b**,” as follows:

b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131, or before May 3, 2006, meets the requirements in 10 CFR ~~35.930 or 35.934~~ 35.390 or 35.394, or meets equivalent agreement state requirements; or

ITEM 40. Amend subrule **41.2(82)**, paragraph “**c**,” subparagraph (2), introductory paragraph, as follows:

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)“a” or “b” or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930 or 35.934~~ 35.390 or 35.394, or equivalent agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131. The work experience must involve:

ITEM 41. Amend subrule **41.2(82)**, paragraph “**c**,” subparagraph (3), as follows:

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)“c”(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(82), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930 or 35.934~~ 35.390 or 35.394, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)“b” must also have experience in oral administration of greater than 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131.

ITEM 42. Amend subrule **41.2(89)**, paragraphs “**a**,” “**b**,” and “**c**,” as follows:

a. Is an authorized user under 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, for uses listed in 41.2(89), or meets equivalent agreement state requirements; or

b. Is an authorized user under 41.2(70) or 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940 or 35.960~~ 35.490 or 35.690, or meets equivalent agreement state requirements, and who meets the requirements in 41.2(89)“d”; or

c. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73), or before May 3, 2006, meets the requirements in 10 CFR ~~35.940 or 35.960~~ 35.490 or 35.690, and who meets the requirements in 41.2(89)“d”; or

ITEM 43. Amend subrule **41.2(89)**, paragraph “**d**,” subparagraph (2), introductory paragraph, as follows:

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, or equivalent agreement state requirements, in the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 41.2(69) or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390 must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The work experience must involve:

ITEM 44. Amend subrule **41.2(89)**, paragraph “**d**,” subparagraph (3), as follows:

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)“b” or “c,” and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(89), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, or equivalent agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69), or before May 3, 2006, meets the requirements in 10 CFR ~~35.930~~ 35.390, must have experience in administering dosages of

either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.

ITEM 45. Amend subrule **41.3(6)**, paragraph “**d**,” as follows:

d. Be certified by the Canadian College of ~~Medical Physics~~ Physicists in Medicine; or

ITEM 46. Amend subrule **41.3(7)**, paragraph “**a**,” as follows:

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures ~~and~~, be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable, and hold a current permit to practice in radiation therapy.

ITEM 47. Amend subrule **41.6(1)** as follows:

Amend the following definition:

“Average glandular dose” means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. ~~The maximum average glandular dose should be 6 milliGray (0.6 rad) or less for a 2-view examination of the breast. For a 50 percent–50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy).~~ See also: “Dose.”

Adopt the following new definitions in alphabetical order:

“Annually” means within 10 to 14 months of previous occurrence.

“Computed radiography mammography” means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

“Direct detector technology” means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

“Full field digital mammography” means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18 × 23 cm to allow imaging the average size breast in a single exposure.

“Provisional certification” means the six-month certification time period in which a facility has to complete the accreditation/certification process.

“Reinstatement” means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

“Soft copy review workstation” means a configuration of two 5 megapixel monitors used for the interpretation of full field digital mammogram images.

ITEM 48. Amend subrule **41.6(2)**, paragraph “**b**,” subparagraphs **(6)** and **(8)**, as follows:

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement 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 provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for a one 90-day extension.

ITEM 49. Amend subrule **41.6(2)**, paragraph “**c**,” as follows:

c. ~~Withdrawal~~ Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be ~~withdrawn~~ suspended or revoked 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 certification.

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

(3) An emergency order ~~withdrawing~~ suspending or revoking certification may be issued in accordance with 641—173.3(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~~ 20 working days after the issuance of the order. The order shall be effective during the proceedings.

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

(5) No change.

ITEM 50. Amend subrule **41.6(2)**, paragraph “**d**,” as follows:

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed ~~the same~~ as an initial application. Appropriate corrective actions must be submitted with the application.

(2) No change.

(3) A full certificate ~~of reinstatement~~ shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

ITEM 51. Amend subrule **41.6(2)**, paragraph “**f**,” as follows:

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial ~~registration and at renewal~~ accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. and 2. No change.

3. Each mammography examination must have been interpreted as a “normal” “negative” or “benign” examination.

(2) Provide randomly (~~at least every three years~~), at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)“**f**”(1).

(3) ~~Have the film returned by the agency for inclusion in the patient’s file after quality interpretation by agency radiologists~~ Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality ~~interpretation~~ review process as set forth in 641—subparagraph 38.8(1)“b”(2).

(5) Be provided with a written explanation of the results of the quality ~~evaluation~~ review process which will accompany the returned mammograms referred to in 41.6(2)“**f**”(3).

ITEM 52. Amend subrule **41.6(2)** by adopting new paragraph “**g**” and relettering existing paragraph “**g**” as “**h**”:

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

ITEM 53. Amend subrule **41.6(2)** by adopting new paragraph “**i**” as follows:

i. Soft copy review workstation requirements. Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two 5 megapixel monitors. The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer’s quality control manual or that outlined by the image receptor manufacturer’s designated soft copy review workstation quality control manual.

ITEM 54. Amend subrule **41.6(3)**, paragraph “**a**,” subparagraph (1), numbered paragraphs “**2**” to “**4**,” as follows:

2. Either:

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic

interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)"a";

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the ~~three years~~ 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; ~~and~~

4. Unless the exemption in 41.6(3)"a"(3)"2" applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

ITEM 55. Amend subrule **41.6(3)**, paragraph "**a**," subparagraph (1), by adopting new numbered paragraph "**5**" as follows:

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality. An interpreting physician previously qualified to interpret full field digital mammography in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa full field digital mammography interpretation.

ITEM 56. Amend subrule **41.6(3)**, paragraph "**a**," subparagraph (2), as follows:

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"a"(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter immediately preceding the inspection or any date during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period;

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)"a"(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period; ~~and.~~

~~3. Before an interpreting physician may begin independently interpreting mammograms produced by screen film or full field digital mammographic modalities, the interpreting physician shall have at least 8 hours of category 1 continuing medical education credits in the mammographic modality. An interpreting physician who has previously qualified to interpret digital mammography in another state will have six months to complete this requirement. The six month time frame starts when the interpreting physician commences Iowa digital mammography interpretation.~~

~~3.~~ 3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)"a"(2)"2" even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

ITEM 57. Amend subrule **41.6(3)**, paragraph "**b**," subparagraph (2), as follows:

(2) Mammography requirements. ~~Prior to April 28, 1999, have~~ Have qualified as a radiologic technologist under 41.6(3)"b" before April 28, 1999, 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:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants, ~~and for full field digital mammography training, physics shall be included;~~

2. No change.

3. ~~At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography examinations. The 8 hours shall not include hours derived from performance of supervised examinations; and~~ Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

ITEM 58. Amend subrule **41.6(3)**, paragraph “b,” subparagraph (3), as follows:

(3) Continuing education requirements:

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)“b”(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months immediately preceding the date of the facility’s annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in , during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. No change.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)“b”(3)“1” shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous ~~three years~~ 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. ~~Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)“b”(2)“3,” the technologist shall have at least 8 hours of continuing education in the new modality. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.~~

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

ITEM 59. Amend subrule **41.6(3)**, paragraph “b,” subparagraph (4), as follows:

(4) Continuing experience requirements.

1. Following the second anniversary date ~~of the end of the calendar quarter~~ in which the requirements of 41.6(3)“b”(1) and (2) were completed ~~or October 28, 1999, whichever is later,~~ the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, immediately preceding the date of the facility’s annual inspection or the last day of the calendar quarter preceding the inspection or any date in during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. No change.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

ITEM 60. Amend subrule **41.6(3)**, paragraph “c,” subparagraph (2), numbered paragraph “2,” as follows:

2. Prior to April 28, 1999, have:

- A bachelor’s degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics; ,
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities, ~~and~~ .

- ~~Have experience~~ Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

- Received at least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.

ITEM 61. Amend subrule **41.6(3)**, paragraph “c,” subparagraph (3), as follows:

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date ~~of the end of the calendar quarter~~ in which the requirements of 41.6(3)“c”(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, immediately preceding the date of the facility’s annual inspection or the last day of the calendar quarter preceding the inspection or any date in during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course ~~can~~ shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date ~~of the end of the calendar quarter~~ in which the requirements of this subrule were completed ~~or April 28, 1999, whichever is later~~, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, immediately preceding the date of the facility’s annual MQSA inspection or the last day of the calendar quarter immediately preceding the inspection or any date in during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days ~~can~~ shall be counted towards this requirement.

3. ~~Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under this subrule, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.~~

ITEM 62. Amend subrule **41.6(4)**, paragraph “a,” as follows:

a. The facility ~~of the performing the~~ current mammography examination must make all reasonable efforts to obtain the patient’s recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from ~~others~~ other facilities, for comparison with the current mammography records.

ITEM 63. Amend subrule **41.6(4)**, paragraph “b,” subparagraph (8), introductory paragraph, as follows:

(8) A separate and distinct section entitled, “~~Overall Final Assessment~~” with ~~findings classified in one of the following categories or an approved equivalent~~ the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

ITEM 64. Amend subrule **41.6(4)**, paragraph “b,” subparagraph (8), numbered paragraph “6,” as follows:

6. ~~In cases where no final assessment category can be assigned due to incomplete workup,~~ “Incomplete: Need additional imaging evaluation” shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

ITEM 65. Amend subrule **41.6(4)**, paragraph “c,” subparagraphs (2) and (3), as follows:

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service ~~or not less than ten years, as long as the patient continues consecutive mammograms. if~~ If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the ~~60-month period~~ retention period, the records must be transferred to the patient or patient’s physician or other mammographic facility.

ITEM 66. Amend subrule **41.6(5)**, paragraph “e,” introductory paragraph, as follows:

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film–screen mammography shall include but not be limited to:

ITEM 67. Amend subrule **41.6(5)**, paragraph “g,” as follows:

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer’s quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a ~~4.5~~ 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 ~~mrad (millirad)~~ millirad for film–screen units with no grids, ~~or 300 mrad~~ millirad for film–screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5)“k.” If the results fall outside the acceptable range, the test shall be repeated. ~~¶ For film–screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted.~~ For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

ITEM 68. Amend subrule **41.6(5)**, paragraph “h,” introductory paragraph and subparagraph (2), as follows:

h. Retake analysis program—film–screen and full field digital.

(2) All retakes shall be logged including date, technologist’s name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.

ITEM 69. Amend subrule **41.6(5)**, paragraph “i,” subparagraph (3), as follows:

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, and notifying other interpreting physicians of the results and the facility aggregate results. If follow–up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow–up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

ITEM 70. Amend subrule **41.6(5)**, paragraph “k,” subparagraph (1), numbered paragraph “1,” as follows:

1. The base plus fog density shall be ~~within~~ below plus 0.03 of the established operating level.

ITEM 71. Amend subrule **41.6(5)**, paragraph “k,” subparagraph (4), numbered paragraph “3,” as follows:

3. Compression device performance. ~~A compression force of at least 25 pounds (111 newtons) for 15 seconds shall be provided. Effective October 28, 2002, the~~ The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

ITEM 72. Amend subrule **41.6(5)**, paragraph “k,” subparagraph (7), by adopting new numbered paragraph “3” as follows:

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer’s quality control manual or in accordance with the appropriate FDA–approved alternative requirements.

ITEM 73. Amend subrule **41.6(5)**, paragraph “k,” subparagraph (8), numbered paragraph “2,” as follows:

2. The results of all tests conducted by the facility in accordance with 41.6(5)“k”(1) through (7) for film–screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer’s quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

ITEM 74. Amend subrule **41.6(5)**, paragraph “k,” subparagraph (9), as follows:

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted ~~whenever a new~~

~~unit or processor is installed at new installations, a unit or processor is disassembled and reassembled at disassembly, at reassembly, at the same or a new location, or when major components of a mammography unit or processor equipment are changed or repaired.~~ These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

ITEM 75. Amend subrule **41.6(6)** as follows:

Amend paragraph **“t,”** catchwords, as follows:

t. Mobile units and vans—~~film screen.~~

Adopt **new** paragraph **“u”** as follows:

u. Mobile units and vans—full field digital. Appropriate manufacturer’s quality control manual procedures and criteria shall be met.

ITEM 76. Amend subrule **41.7(1)** by adopting the following **new** definitions in alphabetical order:

“Procedure” means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

“Qualified training physician” means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

ITEM 77. Amend subrule **41.7(2)**, paragraph **“b,”** subparagraph **(5)**, as follows:

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

ITEM 78. Amend subrule **41.7(2)**, paragraph **“c,”** as follows:

c. ~~Withdrawal~~ Suspension, revocation, or denial of authorization.

(1) Authorization may be ~~withdrawn~~ suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial, ~~or withdrawal~~ suspension, or revocation of authorization.

(3) An emergency order ~~withdrawing~~ suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within ~~five~~ 20 working days after the issuance of the order. The order shall be effective during the proceedings.

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

ITEM 79. Amend subrule **41.7(2)**, paragraph **“d,”** subparagraphs **(2)** and **(3)**, as follows:

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A ~~certificate of full~~ reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

ITEM 80. Amend subrule **41.7(3)**, paragraph **“a,”** subparagraph **(1)**, numbered paragraphs **“2”** and **“4”** to **“6,”** as follows:

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under ~~41.6(3)“a”~~ 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for mammographic interpretation, be experienced as noted in ~~“2”~~ 41.7(3)“a”(1)“2” above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

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

~~6~~ 5. Shall be responsible for the supervision of the radiologic technologist ~~and the medical physicist~~ during the procedure.

ITEM 81. Amend subrule **41.7(3)**, paragraph **“a,”** subparagraph **(2)**, as follows:

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year ~~or requalify as specified above in 41.7(3)“a”(1).~~ If experience is not maintained, the physician must requalify by performing 3 procedures under

direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every ~~three years~~ 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

ITEM 82. Amend subrule **41.7(3)**, paragraph “b,” subparagraph (1), as follows:

Amend numbered paragraph “3” as follows:

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to ~~interpret mammography~~ perform stereotactic biopsy procedures according to ~~41.6(3)“a”~~ 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

Adopt new numbered paragraph “5” as follows:

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

ITEM 83. Amend subrule **41.7(3)**, paragraph “b,” subparagraph (2), as follows:

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 ~~supervised~~ procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every ~~three years~~ 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

ITEM 84. Amend subrule **41.7(3)**, paragraph “c,” subparagraph (1), numbered paragraphs “4” and “7” to “10,” as follows:

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to ~~41.6(3)“a”~~ 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

~~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~~ 7. Must be responsible for the supervision of the radiologic technologist ~~and the medical physicist~~ during the procedure.

~~10~~ 8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

ITEM 85. Amend subrule **41.7(3)**, paragraph “c,” subparagraph (2), as follows:

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 ~~supervised~~ procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every ~~three years~~ 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

ITEM 86. Amend subrule **41.7(3)**, paragraph “**d**,” subparagraph (1), numbered paragraphs “**2**,” “**5**,” and “**7**” to “**10**,” as follows:

~~2. Must have evaluated at least 240 mammograms per year in the prior two years~~ 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”

~~5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)“a”~~ 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

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

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

~~9~~ 7. Must be responsible for the supervision of the radiologic technologist ~~and the medical physicist during the procedure.~~

~~10~~ 8. Must be responsible for post-biopsy management of the patient.

ITEM 87. Amend subrule **41.7(3)**, paragraph “**d**,” subparagraph (2), as follows:

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least ~~240 mammograms per year~~ 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)“a.”

2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 ~~supervised procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.~~

3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every ~~three years~~ 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

ITEM 88. Amend subrule **41.7(4)**, paragraph “**b**,” as follows:

b. Must ~~meet the following initial requirements:~~

(1) ~~Prior to July 1, 1998, have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(3)“a” and 41.7(4)“b.”~~

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

ITEM 89. Amend subrule **41.7(4)**, paragraph “**c**,” subparagraph (2), as follows:

(2) Following the third anniversary in which the requirements of this subrule were met, Have ~~have~~ obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics ~~in~~ during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

ITEM 90. Amend subrule **41.7(5)**, paragraph “**b**,” subparagraphs (1) and (2), as follows:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a ~~qualified physician or technologist~~ qualified under rule 641—41.7(136C).

(2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.

ITEM 91. Amend subrule **41.7(5)** as follows:

Amend paragraph “**c**” as follows:

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, Have have performed an average of at least 12 stereotactically guided breast biopsies per year after initial qualifications are met or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a qualified physician or radiologic technologist qualified under 41.7(3) or 41.7(5).

(2) Following the third anniversary in which the requirements of this subrule were met, Have have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics in during the previous 36 months after initial qualifications are met or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months, immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. The requirements of In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)"b"(4)"1" do not apply in this case.

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

Rescind paragraph "d."

ITEM 92. Amend subrule **41.7(6)**, paragraph "a," subparagraph (2), as follows:

(2) The name of the patient and one additional patient identifier.

ITEM 93. Amend subrule **41.7(7)**, paragraph "b," as follows:

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified ~~radiation~~ medical physicist who is capable of establishing and conducting the program.

ITEM 94. Amend subrule **41.7(7)** by adopting the following new paragraph "c" and relettering existing paragraphs "c" to "f" as "d" to "g":

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

- (1) Quality assurance activities including the medical audit,
- (2) Oversight of the quality control program, and
- (3) Supervision of the radiologic technologist(s) and the medical physicist.

ITEM 95. Amend subrule **41.7(7)**, relettered paragraph "d," as follows:

d. Under the direction of the supervising physician, the ~~radiation~~ medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

- Digital - X-ray field must not extend beyond the image receptor by more than 5 mm on any side.
- Film-screen - On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.
- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- Digital - Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.
- Film-screen - Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

4 5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

5 6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

6 7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

7 8. Image quality evaluation.

• Digital - Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

• Film-screen - Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.

• Failures must be corrected before further procedures are performed.

8 9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

9 10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

10 11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

11. Evaluation of the facility's technologist quality control program.

(2) and (3) No change.

ITEM 96. Amend subrule **41.7(7)**, relettered paragraph "e," as follows:

e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.

(2) Visual checklist (monthly). Any failed items must be corrected within 30 days.

(3) Phantom image (weekly).

1. Digital - Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.

2. Film-screen - Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density difference must be within +/- .05 of the established aim.

3. Failures must be corrected before further procedures are performed.

(4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.

(5) Processor sensitometry (daily before use with systems utilizing film).

ITEM 97. Amend subrule **41.7(7)**, relettered paragraph "f," as follows:

f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.

ITEM 98. Amend subrule **41.7(7)**, relettered paragraph “g,” as follows:

g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of ~~an Iowa-approved~~ a medical physicist qualified under 41.7(4).

ITEM 99. Amend subrule 42.1(1) as follows:

42.1(1) Applicability. Except as otherwise specifically provided, these rules apply to all individuals who operate as a diagnostic radiographer, nuclear medicine technologist, radiologist assistant, podiatric radiographer, or radiation therapist as defined below.

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

ITEM 100. Amend subrule **42.1(2)** as follows:

Amend the following definitions:

“Clinical podiatric sponsor” means a person who is licensed under Iowa Code chapter 149 and who is supervising a podiatric radiography student.

“Diagnostic radiographer” means an individual, other than a licensed practitioner, ~~or~~ podiatric radiographer, or dental assistant with radiography qualification, who applies X-radiation to the human body for diagnostic purposes while under the supervision of a licensed practitioner or registered nurse under 641—subparagraph 41.1(3)“a”(7). 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 only the following body parts: chest, extremities (upper and lower), spine, or sinus. This individual is restricted to performing radiography in that area of the facility specifically designed for X-ray. This individual may not perform pediatric radiography (children under three years of age) without additional training in pediatric radiography taken as a part of the basic limited training or a specifically approved training program (see 42.2(6)).

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

~~“Podiatry assistant~~ Podiatric radiographer” means an individual employed in a podiatry office who performs podiatric radiography but not CT or fluoroscopy.

“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: advanced CPR, educator’s programs, management programs, personal improvement, for example.

“Supervision” means responsibility for and control of quality, radiation safety and protection, and technical aspects of the application of ionizing radiation to human beings for diagnostic or therapeutic purposes. Indirect supervision is being physically present in the immediate vicinity and able to assist if needed. Direct supervision is physically observing and critiquing the actual procedure and giving immediate assistance if required.

Add the following new definitions in alphabetical order:

“Directly related” means covering a subject listed in the training requirements for a specific certification.

“Formally educated” means completion of a formal course of training and testing approved by the agency.

ITEM 101. Amend subrule **42.2(1)**, paragraph “h,” as follows:

h. ~~Work~~ As a diagnostic radiographer, work only under the supervision of a licensed practitioner as defined in 641—38.2(136C); as a nuclear medicine technologist, work only under the supervision of an authorized user as defined in 641—41.2(136C); or as a radiation therapist, work only under the supervision of a licensed physician or authorized user as defined in 641—41.2(136C).

ITEM 102. Amend subrule **42.2(1)**, paragraph “j,” as follows:

j. For ~~podiatry assistants~~ podiatric radiographers only, follow the application process in 42.7(4).

ITEM 103. Amend subrule **42.2(2)**, paragraphs “a,” “b,” and “d,” as follows:

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

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

d. Submitting false information in order to obtain certification or renewal certification as a diagnostic radiographer, ~~podiatric assistant radiographer~~, radiologist assistant, nuclear medicine technologist, or radiation therapist.

ITEM 104. Amend subrule **42.2(2)**, paragraph “**e**,” subparagraphs **(1)**, **(3)**, and **(6)**, as follows:

(1) Any medical condition which may impair or limit the individual’s ability to perform diagnostic radiography, nuclear medicine procedures, or radiation therapy;

(3) A misdemeanor or felony which may impair or limit the individual’s ability to perform diagnostic radiography, nuclear medicine procedures, or radiation therapy;

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

ITEM 105. Amend subrule **42.2(2)**, paragraph “**g**,” as follows:

g. Failing to pay fees or costs required to meet the requirements of this chapter. Penalties for working without a current permit will be considered on a case-by-case basis.

ITEM 106. Amend subrule **42.2(3)**, paragraph “**a**,” subparagraph **(9)**, as follows:

(9) ~~Podiatry assistant~~ Podiatric radiographer: See 42.7(5).

ITEM 107. Amend subrule **42.2(3)**, paragraph “**b**,” subparagraphs **(5)** and **(6)**, as follows:

(5) No continuing education credit is approved for passing an initial certification examination or for basic CPR, hands-on practice, mandatory abuse reporting, or ultrasound or MRI courses that are less than 50 percent directly related to radiography, nuclear medicine, or radiation therapy.

(6) One-half hour of credit will be granted for each hour of formal demonstration of equipment by the application specialist. Content must be company-specific but not site-specific. Credit is limited to 50 percent of the total hours required.

ITEM 108. Amend subrule **42.2(3)**, paragraph “**e**,” as follows:

e. Proof of continuing education must be maintained for at least three years. Proof of continuing education may be a sign-in sheet, certificate, or answer sheet. It must be signed and dated by the presenter, program representative, or the individual’s supervisor. Individuals authorized for mammography must ~~meet~~ meet the records requirements in 641—41.6(136C) and 641—41.7(136C).

ITEM 109. Amend subrule **42.2(3)**, paragraph “**g**,” subparagraphs **(2)** and **(3)**, 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 ~~plus 3.0 additional penalty hours for limited technologists and 6.0 additional penalty hours for general technologists and 1.0 hour for podiatric assistants~~ and the fee required in 641—paragraph 38.8(6)“c” shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and ~~additional penalty hours~~ 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, nuclear medicine technologist, ~~radiologist assistant~~, or podiatric radiographer in Iowa.

(3) Once certification has been terminated, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must submit proof of continuing education hours ~~plus penalty hours~~ and shall submit a late fee as set forth in 641—paragraph 38.8(6)“c” in addition to the annual fee set forth in 641—paragraph 38.8(6)“a” in order to obtain reinstatement of certification.

ITEM 110. Amend subrule **42.2(4)**, paragraph “**a**,” subparagraph **(4)**, as follows:

(4) ~~Podiatry assistants~~ Podiatric radiographers must meet the requirements of 42.7(6).

ITEM 111. Amend subrule **42.2(4)**, paragraph “**e**,” introductory paragraph, as follows:

e. Upon the completion of the recertification training, the following must be submitted:

ITEM 112. Amend subrule **42.2(6)**, paragraph “**a**,” as follows:

a. Any individual wishing to train an individual as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist must submit a training program to the agency for approval. This provision includes individuals providing clinical training for out-of-state students. For radiologist assistants, see 641—

42.6(136C). For podiatric radiographers, see 641—42.7(136C). No training may be started until written approval from the agency is received. The training request must provide, at a minimum, the following:

(1) An outline of the didactic and clinical studies to meet the requirements of 42.3(1), 42.4(2), or 42.5(2), as applicable.

(2) Listed body parts to be taught if this is a limited radiography training program. Procedures are limited to chest, extremities, spinal, or sinus radiography.

(3) Proof that ~~the~~:

1. The instructor of a general training program meets the requirements of this chapter as a two-year ~~trained~~ educated diagnostic radiographer, nuclear medicine technologist, or radiation therapist holding a current Iowa general permit to practice and having at least two years of current experience or is a licensed physician trained in the specific area of ~~competence~~ the training program.

2. The instructor of a limited training program meets the following:

• The principal instructor of a limited training program is a general radiographer holding a current Iowa permit to practice and having at least two years of current experience or is a licensed physician trained in the specific area of the training program.

• The on-site clinical instructor is a general radiographer holding a current Iowa permit to practice and having at least two years of current experience or is a limited radiographer holding a current Iowa permit to practice in the area of instruction and having at least two years of current experience. On-site clinical instructors shall be supervised by the principal instructor.

(4) No change.

(5) A description of the testing to be used to determine proficiency of the didactic portion and the mechanism to be used to determine clinical competency. All clinical competency testing shall be conducted by the principal instructor.

(6) A statement of permission to allow a representative of the agency to periodically evaluate the progress of the student. The agency will evaluate all non-school students.

(7) A statement that the student will be directly supervised until the student's competency is documented and indirectly supervised after the student's competency is documented.

ITEM 113. Amend subrule 42.3(1), paragraph "b," subparagraph (1), numbered paragraph "7," as follows:

7. Clinical experience sufficient to demonstrate competency in the application of the above as specified by the department. Clinical experience must be directly supervised by a two-year ~~trained~~ educated general radiographer, licensed physician, chiropractor, or podiatrist who physically observes and critiques the actual X-ray procedures.

ITEM 114. Amend subrule 42.3(3), paragraph "a," introductory paragraph, as follows:

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

ITEM 115. Amend rule 641—42.7(136C), catchwords, as follows:

641—42.7(136C) Specific requirements for podiatric ~~assistants~~ radiographers.

ITEM 116. Amend subrule 42.7(1), paragraph "a," subparagraph (2), numbered paragraphs "3" and "4," as follows:

3. Be directly supervised by a podiatrist, general radiographer, or certified podiatric ~~assistant~~ radiographer; and

4. Not be started until notification of the desire to conduct a clinical training program has been submitted to this agency and verification of approval has been received by the podiatric sponsor; and

ITEM 117. Amend subrule 42.7(3), paragraph "a," as follows:

a. Students enrolled and participating in an approved course of clinical study for ~~podiatry assistants~~ podiatric radiographers or an approved school of medicine, osteopathy, or podiatry who, as part of their course of study, may apply ionizing radiation to a human being while under the supervision of a licensed practitioner.

ITEM 118. Amend subrule 42.7(5), paragraph "c," as follows:

c. Proofs of completion shall be retained by the podiatric ~~assistant~~ radiographer for four years.

ITEM 119. Amend subrule 44.4(6), paragraph "b," subparagraph (2), as follows:

(2) Pay annually a renewal fee of \$150 or a mitigation system installation surcharge fee of \$40 per mitigation system installed (as defined in 641—44.2(136B)) costing more than \$200, whichever is greater. With each renewal, a credentialed person must submit legal documentation of the number of mitigation systems installed the previous credentialing year. ~~This number will be used to calculate the renewal fee.~~ If an individual decides not to renew credentials the following year, all surcharge fees are to be paid in full within 30 days of the date of expiration of the credentials.

ITEM 120. Amend subrule **46.5(8)**, paragraph “**d**,” subparagraph (2), as follows:

(2) Provide disposable eyewear in the tanning room at all times and post a sign stating that the disposable eyewear is available and that eyewear must be worn.