

## **PUBLIC HEALTH DEPARTMENT [641]**

### **Adopted and Filed**

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 38, "General Provisions for Radiation Machines and Radioactive Materials"; Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials"; Chapter 40, "Standards for Protection Against Radiation"; Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"; Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists"; Chapter 43, "Minimum Requirements for Radon Testing and Analysis"; Chapter 44, "Minimum Requirements for Radon Mitigation"; Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations"; and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following itemize the adopted changes.

Items 1, 3 to 5, 9 to 11, 14, 16, 19 to 21, 23 to 25, 29, 30 to 32, 35, 59, 61 to 63, 65, 68, 70, and 73 to 76 amend the rules to reflect current federal regulations, correct cross references, addresses, and catchwords and general errors, and clarify wording.

Item 2 amends the definition of "major processor" to correct a cross reference and amends the definition of "written directive" to include orders for radiopharmaceuticals, which had been previously omitted. Item 2 also adds definitions for "direct supervision" and "high-level radioactive waste," which were not defined previously, in order to make the use uniform in all chapters.

Items 6, 7, 8, 12, and 13 address fees.

Items 15, 57, and 58 rescind subrules the content of which has been incorporated into Chapters 38 and 39 in order to make Chapters 38 and 39 stand-alone chapters. Responsibility for these chapters has been moved to another bureau.

Items 17, 18, 33, and 46 to 48 place agency policies into the rules.

Item 22 changes where the individual monitoring device should be worn in accordance with industry standards.

Item 26 clarifies how long records should be kept.

Item 27 adds new requirements for fluoroscopic equipment. This change is the result of documented burns resulting from radiation exposure during medical procedures.

Item 28 and 51 address items new to the industry.

Item 34 changes the frequency of image monitoring to ensure image quality.

Items 36 to 43 amend Chapter 41 to allow training hours approved by the agency to be used to meet requirements. This allows hours that are not submitted specifically to the AMA to be used to meet requirements.

Item 45 adds a requirement that physicians interpreting radiographs in Iowa show proof of Iowa licensure. This is to ensure that physicians working temporarily in Iowa are qualified.

Items 49, 50, 52 to 56 clarify training programs for operators under Chapter 42.

Items 60, 64, 66, 67, 69, 71, and 72 amend wording to reflect the new definition of "direct supervision." Items 60 and 71 also rescind definitions of "personal supervision."

Items 77 and 78 replace current lists of photosensitizing agents with a more user-friendly list and require that this list be used by operators. During inspections of facilities, it was noted that consumers were not reading the current lists because of the terminology used.

The State Board of Health adopted these amendments at the Board's regular meeting on March 13, 2002.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on February 6, 2002, as **ARC 0694B**. A public hearing was held on February 26, 2002, at 8:30 a.m. in the conference Room, Department of Public Health, 401 S.W. 7<sup>th</sup> Street, Suite D, Des Moines, Iowa. There were no persons in attendance at the hearing. Five sets of written comments were received, reviewed, and incorporated as appropriate. The changes made from the Notice of Intended Action are listed below.

1. The definitions of "working level" and "working level month" in Item 1. are not rescinded. These definitions are required in order for our rules to be compatible with federal regulations.
2. In Item 20, the term "applicable provision" is changed to "applicable provisions" to cover all items contained in the federal standards.
3. In Item 27, all references to "rads" are changed to "rad" which is the proper term for both singular and plural.
4. Noticed Item 29 is withdrawn for further review of new technology.
5. In Item 76, the monitoring device under "record type" is moved to the proper place in addition to being amended.

These amendments will become effective May 8, 2002.

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

The following amendments are adopted.

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

**38.1(2)** All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 4, 2001~~ May 8, 2002.

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

Rescind the definitions of "working level" and "working level month."

Amend the following definitions:

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

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

1. to 6. No change.

Adopt the following new definitions in alphabetical order:

"Direct supervision" means guidance and instruction by a qualified individual who is physically present and watching the performance of the radiological operation or procedure and in such proximity that contact can be maintained and immediate assistance can be given as required.

"High-level radioactive waste " or "HLW" mean: (1) irradiated reactor fuel; (2) liquid wastes resulting from the operator of the first cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and (3) solids into which such liquid wastes have been converted.

ITEM 3. Amend subrule **38.4(4)**, paragraph "**b**," introductory paragraph, as follows:

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

ITEM 4. Rescind rule **641—38.5(136C)**.

ITEM 5. Amend subrule **38.7(1)** as follows:

**38.7(1)** All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, ~~Lucas State Office Building, Des Moines, Iowa 50319~~ 401 SW 7<sup>th</sup> Street, Suite D, Des Moines, Iowa 50309-4611.

ITEM 6. Amend subrule **38.8(1)**, paragraph "**a**," introductory paragraph, as follows:

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

ITEM 7. Amend subrule **38.8(1)**, paragraph "**b**," subparagraph **(1)**, as follows:

(1) Mammography unit inspections fees:

- \$850 for the first unit and, if the facility has additional units at the address of the first unit, a fee of \$300 for each additional unit: or

- \$850 per portable unit for each site where the unit is off-loaded and used and where the processing and patient films are stored; or
- Dollar amount to be determined and justified by the department on a case-by-case basis for facilities which do not meet the above criteria;
- \$400 for the second facility follow-up visit to review or determine the corrective action taken to address noncompliances.

ITEM 8. Amend subrule **38.8(1)** by adopting new paragraphs "d" and "e" as follows:

d. Each person engaged in providing health physics services in mammography in Iowa, who meets the requirements of 641—paragraph 41.6(3)"c" and is deemed qualified by this agency, must submit a \$35 annual listing fee to this agency.

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

ITEM 9. Amend subrule **38.8(2)**, paragraph "a," subparagraph (1), as follows:

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31. The radioactive materials fee schedule is available through the agency.

ITEM 10. Amend subrule **38.8(2)**, paragraph "b," subparagraph (1), as follows:

(1) After completion of an inspection, an inspection fee shall be assessed to a facility based on the fees for inspection which shall not exceed those found in 10 CFR 170.32 entitled, "Schedule of Fees for Health and Safety, and Safeguards Inspections for Materials Licenses." The radioactive materials fee schedule is available through the agency.

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

b. A fee of \$25 shall be submitted in order to replace lost identification cards issued to industrial radiographers by the agency pursuant to ~~641—subrule 45.11(3)~~ 641—subrule 45.1(10).

ITEM 12. Amend subrule **38.8(6)**, paragraph "a," as follows:

a. Annual fee. Each individual must submit a \$45 initial fee for the first year and \$35 annually. These fees are nonrefundable.

ITEM 13. Amend subrule **38.8(6)**, paragraph "d," as follows:

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

ITEM 14. Amend subrule **38.8(8)**, paragraph "b," as follows:

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

ITEM 15. Rescind and reserve subrules **38.8(9)** and **38.8(10)**.

ITEM 16. Amend rule **641—38.9(136C)**, catchwords, as follows:

~~641—38.9(136C) Procedure for imposing requirements by order, or for modification, suspension, or revocation of a license, registration, or certificate or for imposing civil penalties. Administrative enforcement actions.~~

ITEM 17. Amend subrule **38.9(2)** by adopting **new** paragraphs "c" to "f" as follows:

- c. Violations are categorized according to five levels of severity, which are:
  - 1. Severity Levels I and II: Violations are of very significant regulatory concern involving actual or high potential impact on the public health and safety.
  - 2. Severity Level III: Violations are cause for significant concern.
  - 3. Severity Level IV: Violations are less serious but are of more than minor concern and that, if left uncorrected, could lead to a more serious health and safety concern.
  - 4. Severity Level V: Violations are of minor safety or environmental concern.
- d. A group of violations may be evaluated in the aggregate and assigned a single higher severity level if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.
- e. The severity level of a violation may be increased if the violation can be considered a repetitive violation. The term "repetitive violation" or "similar violation" means a violation that reasonably could have been prevented by a regulated entity's corrective action for a previous violation normally occurring within the past two years of the inspection at issue or the period within the last two inspections, whichever is longer.
- f. The severity level of a violation may be increased if the violation involves casual disregard of requirements, deception, or other indications of willfulness. The term "willfulness" is that characteristic of violations ranging from deliberate intent to violate or falsify to intentional disregard for regulatory requirements.

ITEM 18. Adopt **new** subrule **38.9(8)** as follows:

38.9(8) Impounding. The agency may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of Iowa Code chapter 136C, or any rules, license or registration conditions, or orders issued by this agency.

a. If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give to either the owner or the possessor of the source of radiation written notice of the intention to impound the source of radiation.

(1) Either the owner or the possessor shall have 20 days from the date of personal service of certified mailing to request a hearing, except in the case where the regulated entity has consented in writing to the impoundment.

(2) If a hearing is requested, the agency will issue an order designating the time and place of hearing.

b. At the agency's direction, the impounded sources of radiation may be disposed of by:

(1) Returning the source of radiation to a properly licensed or registered owner that did not cause the emergency;

(2) Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or

(3) Selling, destroying, or disposing of the source of radiation in another manner within the agency's discretion.

ITEM 19. 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 ~~July 4, 2001~~ May 8, 2002.

ITEM 20. Amend rule ~~641—39.5(136C)~~ as follows:

~~641—39.5(136C)~~ Transportation of radioactive material. All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the applicable provisions contained in 10 CFR Part 71 ~~as it applies to the state of Iowa~~ and 49 CFR Parts 170 through 189.

ITEM 21. Amend rule ~~641—40.36(136C)~~ by adopting the following **new** subrule:

**40.36(5)** After replacement, each film badge, TLD, or OSL device must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier.

ITEM 22. Amend subrule **40.37(3)**, paragraph "a," as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is ~~typically at the neck (collar)~~; shall be near the midline of the body, under the apron;

ITEM 23. Amend subrules **40.90(1)** and **40.90(2)** as follows:

40.90(1) Each record required by Chapter 40 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform; provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period, or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

40.90(2) The licensee or registrant shall retain the records required by Chapter 40 until the agency terminates each pertinent license or registration requiring the record.

ITEM 24. Amend subrule **40.112(1)**, **introductory paragraph**, as follows:

40.112(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in ~~this~~ subrule 40.112(2). The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 40.86(136C). Each notification and report shall:

ITEM 25. Amend subrule **41.1(1)** as follows:

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 4, 2001~~ May 8, 2002.

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

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

ITEM 27. Amend subrule **41.1(5)** by adopting **new** paragraph "k" as follows:

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the physician performing the procedure must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

ITEM 28. Amend subrule **41.1(9)**, paragraph "b," as follows:

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

ITEM 29. Rescind subrule **41.2(31)** and adopt the following **new** subrule in lieu thereof:

**41.2(31)** Use of radiopharmaceuticals for uptake, dilution, or excretion studies. The licensee may use for uptake, dilution, excretion and imaging studies any unsealed by-product material prepared for medical use that is either:

a. Obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)"j" or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 41.2(67), or an individual under the supervision of either as specified in 41.2(11).

ITEM 30. Rescind subrule **41.2(33)** and adopt the following **new** subrule in lieu thereof:

**41.2(33)** Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies. The licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that is either:

a. Obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)"j" or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements; or

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 an individual under the supervision of either as specified in 41.2(11).

ITEM 31. Adopt **new** subrule **41.2(80)** as follows:

41.2(80) Training for nuclear medicine technologists.

a. Nuclear medicine technologists shall meet the requirements of 641—42.4(136C).

b. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

ITEM 32. Rescind paragraph **41.3(6)"f"**:

ITEM 33. Amend subrule **41.6(1)**, definition of "qualified instructor," as follows:

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

ITEM 34. Amend subrule **41.6(5)**, paragraph "f," subparagraph (2), as follows:

(2) Image quality shall be monitored at least ~~monthly~~ weekly with a phantom and every time the unit is altered including the replacement of parts.

ITEM 35. Amend subrule **41.6(6)**, paragraph "i," subparagraph (2), as follows:

(2) ~~Find~~ Fine adjustment compression controls operable from both sides of the patient.

ITEM 36. Amend subrule **41.7(3)**, paragraph "a," subparagraph (1), as follows:

(1) Initial training and qualifications.

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

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)"b"~~ 41.6(3)"a" and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. to 6. No change.

ITEM 37. Amend subrule **41.7(3)**, paragraph "a," subparagraph (2), numbered paragraph "2," as follows:

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.

ITEM 38. Amend subrule **41.7(3)**, paragraph "b," subparagraph (1), numbered paragraphs "1," and "2," as follows:

1. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

2. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is both qualified to interpret mammography according to ~~41.6(3)"b"~~ 41.6(3)"a" and has performed at least 24 stereotactically guided breast biopsies.

ITEM 39. Amend subrule **41.7(3)**, paragraph "b," subparagraph (2), numbered paragraph "2," as follows:

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.

ITEM 40. Amend subrule **41.7(3)**, paragraph "c," subparagraph (1), numbered paragraphs "1," "2," and "4," as follows:

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

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

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)"b"~~ 41.6(3)"a" and has performed at least 24 stereotactically guided breast biopsies.

ITEM 41. Amend subrule **41.7(3)**, paragraph "c," subparagraph (2), numbered paragraph "2," as follows:

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 which includes post-biopsy management of the patient.

ITEM 42. Amend subrule **41.7(3)**, paragraph "d," subparagraph (1), numbered paragraphs "1," "2," and "4," as follows:

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

2. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

4. 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)"b"~~ 41.6(3)"a" and has performed at least 24 stereotactically guided breast biopsies.

ITEM 43. Amend subrule **41.7(3)**, paragraph "**d**," subparagraph (2), numbered paragraphs "**1**," and "**3**," as follows:

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

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.

ITEM 44. Amend subrule **41.7(5)**, paragraph "**a**," as follows:

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

ITEM 45. Amend ~~641—Chapter 41, Appendix C~~, numbered paragraph "**11**," as follows:

11. The name and address of the ~~individual~~ physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.

ITEM 46. Amend subrule **42.2(2)** by adopting **new** paragraph "**g**" as follows:

g. Failing to pay fees or costs required to meet the requirements of this chapter.

ITEM 47. Amend subrule **42.2(3)**, paragraph "**b**," by adopting **new** subparagraph (5) as follows:

(5) No continuing education credit is approved for passing a certification examination.

ITEM 48. Amend subrule **42.2(3)**, paragraph "**e**," as follows:

e. It is required that proof of receiving continuing education be retained at each individual's place of employment for review by representatives of the department. Proof of continuing education must be maintained for at least three years. 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.

ITEM 49. Rescind subrule **42.2(4)**, paragraph "**d**."

ITEM 50. Adopt **new** subrule 42.2(6) as follows:

**42.2(6)** Training programs.

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. The request must provide the following:

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

(2) Listed body parts to be taught if this is a limited radiography training program.

(3) Proof that the instructor meets the requirements of this chapter as a diagnostic radiographer, nuclear medicine technologist, radiation therapist or is a licensed physician trained in the specific area of competence.

(4) A time schedule of the training program. The projected completion date of the clinical portion of the program or course of study shall be within a time period equal to or less than twice that required for the original program or course of study.

(5) A description of the mechanism to be used to determine competency.

b. Upon the completion of the training program, the following must be submitted to the agency:

(1) A statement of competency from the trainer for each area completed.

(2) A statement of permission to allow a representative of the agency to comprehensively evaluate whether the individual meets the training standard.

ITEM 51. Adopt **new** subrule **42.2(7)** as follows:

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

ITEM 52. Amend subrule **42.3(4)**, paragraph "a," as follows:

a. Students enrolled in and participating in an approved program or approved course of study for diagnostic radiography, or an approved school of medicine, osteopathy, podiatry, and chiropractic; who, as a part of their course of study, apply ionizing radiation to a human being while under the supervision of a licensed practitioner. ~~The projected completion date of the clinical portion of the program or course of study shall be within a time period equal to or less than twice that required for the original program or course of study.~~

ITEM 53. Amend subrule **42.4(2)** by adopting **new** paragraph "d" as follows:

d. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa, agreement state, or U.S. Nuclear Regulatory Commission radioactive materials license. Quality assurance and quality control experience may be directly supervised by a pharmacist who appears as an authorized nuclear pharmacist on an Iowa, U.S. Nuclear Regulatory Commission, or agreement state radioactive materials license.

ITEM 54. Amend subrule **42.4(4)**, paragraph "a," as follows:

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

ITEM 55. Amend subrule **42.5(2)** by adopting **new** paragraph "d" as follows:

d. Clinical experience must be directly supervised by a radiation therapist or radiation oncologist.

ITEM 56. Amend subrule **42.5(4)**, paragraph "a," as follows:

a. Students enrolled in and participating in an approved program or approved course of study for radiation therapy technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radiation therapy to a human being while under the supervision of a licensed physician in the state of Iowa. ~~Clinical experience must be directly supervised by a radiation therapist~~

~~or radiation oncologist who physically observes and critiques the actual radiation therapy procedure.~~

ITEM 57. Rescind subrule **43.4(6)** and adopt the following **new** subrule **43.4(7)** in lieu thereof:

**43.4(6)** Radon certification. Any person wishing to become certified as a radon measurement specialist or radon measurement laboratory is required to pay fees sufficient to defray the cost of administering this chapter. Fees which must be submitted are as follows:

a. Application fee.

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

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

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

c. Annual certification fee.

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

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

d. Each person wishing to give reciprocal recognition of credentials from another jurisdiction must pay the appropriate fees in 43.4(6)"a," "b," or "c."

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

(1) \$15 for each insufficient funds check submitted for payment of radon testing or mitigation fees.

(2) \$25 per month for failure to pay annual radon testing or mitigation fees starting after the annual renewal month.

ITEM 58. Rescind subrule **44.4(6)** and adopt the following **new** subrule **44.4(6)** in lieu thereof:

**44.4(6)** Radon mitigation credentialing. Any person wishing to become credentialed as a radon mitigation specialist shall be required to pay fees sufficient to defray the cost of administering this chapter. Fees which must be submitted are as follows:

a. Application fee.

(1) Each person with Iowa residency wishing certification under the provisions of 641—Chapter 44 shall pay a nonrefundable \$25 application fee.

(2) Each person without Iowa residency wishing certification under 641—Chapter 44 shall pay a nonrefundable \$100 application fee.

b. Annual credentialing fee.

(1) Each individual requesting credentialing must:

1. Pay an initial fee of \$150 which is refundable if credentialing is not completed.

2. Pay annually a renewal fee of \$150 or \$40 per mitigation system installed (as defined in 641—44.2(136B)) costing more than \$200, whichever is 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.

(2) Each person wishing to receive reciprocal recognition of credentialing from another jurisdiction must pay the appropriate fees as outlined in 44.4(6), paragraphs "a" and "b."

c. Examination fee. Each person taking the EPA Radon Proficiency Examination, if it is administered by the Iowa department of public health, shall pay a fee of \$125. The fee must be submitted prior to testing.

ITEM 59. Amend subrule **45.1(1)**, introductory paragraph, as follows:

**45.1(1)** Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 4, 2001~~ May 8, 2002.

ITEM 60. Amend subrule **45.1(2)** as follows:

Rescind the definition of "personal supervision."

Amend the following definition:

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

ITEM 61. Amend subrule **45.1(12)**, paragraph "b," subparagraph (1), as follows:

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

ITEM 62. Amend subrule **45.1(12)**, paragraph "b," subparagraphs (5) to (8) as follows:

(5) If an individual's pocket dosimeter is discharged beyond its range (i.e., goes "off scale"), or if the electronic personal dosimeter reads greater than 200 millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual's film badge, OSL device, or TLD shall be within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each ~~film badge, OSD or TLD~~ individual monitoring device shall be assigned to and worn by only one individual.

(7) Film badges, ~~OSDs~~ OSL devices and TLDs must be replaced at least monthly. ~~After replacement, each film badge, OSD or TLD must be returned to the supplier for~~

~~processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier.~~

(8) If a ~~film badge, OSD or TLD~~ an individual monitoring device is lost or damaged, the worker shall cease work immediately until a replacement ~~film badge, OSD or TLD~~ individual monitoring device is provided and the exposure is calculated for the time period from issuance to loss or damage of the ~~film badge, OSD or TLD~~ individual monitoring device.

ITEM 63. Amend subrule **45.1(12)**, paragraph "e," as follows:

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

ITEM 64. Amend subrule **45.1(13)**, **introductory paragraph**, as follows:

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

ITEM 65. Amend subrule **45.1(17)**, paragraph "a," subparagraph (2), as follows:

(2) A current whole body personnel monitor (TLD, OSL device or film badge) for each individual;

ITEM 66. Amend subrule **45.1(17)**, paragraph "e," as follows:

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

ITEM 67. Amend subrule **45.2(4)**, paragraph "c," as follows:

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

ITEM 68. Amend subrule **45.2(6)**, paragraph "b," subparagraph (1), as follows:

(1) Operating personnel must be provided with ~~either a film badge or a thermoluminescent dosimeter~~ individual monitoring devices in accordance with the appropriate provisions of 641—40.37(136C).

ITEM 69. Amend subrule **45.3(6)**, paragraph "e," as follows:

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

ITEM 70. Amend subrule **45.4(1)**, paragraph "c," as follows:

c. The requirements of ~~45.1(10)~~ 45.1(10)"b"(2) and (3) and 45.1(10)"d"(1)"2" do not apply to nonradiographic uses.

ITEM 71. Amend subrule **45.6(3)** as follows:

Rescind the definition of "personal supervision."

Amend the following definitions:

"Logging assistant" means any individual who, under the ~~personal~~ direct supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 45.6(22).

"Logging supervisor" means the individual who uses sources of radiation or provides ~~personal~~ direct supervision of the utilization of sources of radiation at the well site.

ITEM 72. Amend subrule **45.6(15)**, paragraph "**b**," subparagraph (2), as follows:

(2) Demonstrated competence to use, under the ~~personal~~ direct supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

ITEM 73. Amend subrule **45.6(17)**, paragraph "**a**," as follows:

a. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears ~~either~~ a film badge, OSL device or a thermoluminescent dosimeter (TLD). Each film badge, OSL device or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSL devices and TLDs replaced at least quarterly. After replacement, each film badge, OSL device or TLD must be promptly processed.

ITEM 74. Amend **641—Chapter 45, Appendix A, "II," "C,"** by adopting new numbered paragraph "**4**," as follows:

4. OSL devices

ITEM 75. Amend the following entry in **641—Chapter 45, Appendix C:**

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(12)	Pocket dosimeter readings.	2 years or until disposal is authorized by the agency if dosimeters were used to determine external radiation dose.
	Pocket dosimeter calibrations	2 years.
	<u>Film badge, OSL device, Or TLD reports.</u>	<u>Until disposal is authorized by the agency.</u>
	Alarming ratemeter calibrations.	2 years.
	Alarming ratemeter functions.	2 years.
45.2(6) and	Annual evaluation of enclosed X-ray systems.	2 years.
45.3(8)	<del>Film badge or TLD records.</del>	<del>Until disposal is authorized by the agency.</del>

ITEM 76. Amend rule **641—46.1(136D)**, the first unnumbered paragraph, as follows:

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January 1, 2001~~ May 8, 2002.

ITEM 77. Amend subrule **46.5(1)**, paragraph "**c**," subparagraph (1), as follows:

(1) ~~A~~ The representative list of potential photosensitizing drugs and agents shown in Appendix 1. ~~This list should at least include drugs or agents in the product classes of acne treatment, antibacterials, antibiotics, anticonvulsants, antidepressants, antidiabetics, antihypertensives, dye, estrogen and progesterones, melanogenics, perfumes and toilet articles, tranquilizers, antihistamines and antimicrobials/anti-infectious agents. A partial list of drugs and agents in these product classes is found in Appendices 1A, 1B, and 1C.~~

ITEM 78. Rescind 641—Chapter 46, Appendices 1A to 1C and adopt the following **new** Appendix 1:

### Appendix 1

#### POTENTIAL PHOTSENSITIZING AGENTS

1. Not all individuals who use or take these agents will experience a photosensitive reaction or the same degree of photosensitive reaction. An individual who experiences a reaction on one occasion will not necessarily experience it again or every time.
2. Names of agents should be considered only as examples. They do not represent all the names under which a product may be sold. A more complete list is available from the facility operator.
3. If you are using an agent in any of these classes, you should reduce UV exposure even if your particular medication is not listed.

Acne treatment (Retinoic acid, Retin-A) Psoralens (5-Methoxypsoralen, 8-Methoxypsoralen, 4,5,8-trimethyl-psoralen)

Antibacterials (Deodorant bar soaps, antiseptics, cosmetics, halogenated carbanilides, halogenated phenols, halogenated salicylanilides, bithionol, chlorhexidine, hexachlorophene)

Antibiotics, anti-infectives (Tetracyclines)

Anticonvulsants (carbamazepine, trimethadione, promethazine)

Antidepressants (amitriptyline, Desipramine, Imipramine, Nortriptyline, Protiptyline),  
Tranquilizers, anti-emetics (Phenothiazines)

Antidiabetics (glucose-lowering agents) (sulfonylureas, oral antidiabetics, hypoglycemics)

Antihistamines (diphenhydramine, promethazine, triprolidine, chlorpheniramine)

Anti-inflammatory (piroxicam), Non-steroidal anti-inflammatory drugs (Ibuprofen, Naproxen, Piroxicam)

Antimicrobials (griseofulvin), Sulfonamides ("Sulfa drugs," antimicrobials, anti-infectives)

Atropine-like drugs (anticholinergics, antiparkinsonism drugs, antispasmodics, synthetic muscle relaxants)

Coal tar and derivatives (Denorex, Tegrin, petroleum products used for psoriasis and chronic eczema and in shampoos)

Contraceptives, oral and estrogens (birth control pills, estrogens, progesterones)

Dyes (used in cosmetic ingredients, acridine, anthracene, cosin (lipstick), erythrosine, fluorescein, methyl violet, methylene blue, rose bengal)

Perfumes and toilet articles (musk ambrette, oil of bergamot, oil of cedar, oil of citron, oil of lavender, oil of lemon, oil of lime, oil of rosemary, oil of sandalwood)

Thiazide diuretics ("waterpills")

\_\_\_\_\_  
Stephen C. Gleason, Director

\_\_\_\_\_  
Date