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DEPARTMENT OF PUBLIC HEALTH
STEPHEN C. GLEASON, D.O., director

December 11, 2001

Frederick C. Combs, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Combs

Enclosed is a copy of the proposed revision to the Iowa Radiation Machines and Radioactive Materials Rules. The proposed rules will be available for public comment on February 6, 2002 with a request for comments by February 26, 2002. We request NRC's comments by February 26, 2002. Radiation machine and radioactive materials proposed revisions are identified by item number and underlined/strikeout text.

We believe adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) procedure SA-200.

If you have any questions, please feel free to contact me at 515/281-3478 or email dflater@idph.state.ia.us or Fax 515/725-0318.

Sincerely,

Donald A. Flater, Chief
Bureau of Radiological Health

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PUBLIC HEALTH DEPARTMENT [641]

OSP

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Notice of Intended Action

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 proposed changes.

Items 1, 20, 26, 60, and 77 amend the rules to reflect current federal regulations.
Item 2 rescinds the definition of "working level" which is already defined in Chapter 43 and "working level month" which are already defined in Chapter 44. It also amends the definition of "major processor" to correct a cross-reference that directs the reader to Chapter 38 for additional information. It also amends the definition of "written directive" to include orders for radiopharmaceutials which had been previously omitted. It also adds a definition for "direct supervision" and "high-level radioactive waste" which were not defined previously in order to make the use uniform in all chapters.
Items 3, 11, 37, 41, 43, 44, 45, 71, and 76 correct cross-references.
Item 4 rescinds a rule and consolidates it into 641—38.9 for clarity.
Item 5 corrects the agency address.
Items 6, 12, and 13 add s "nonrefundable" because the cost to issue refund checks exceeds the initial fee.
Items 7 and 8 add new fees for a follow-up visit to verify correction of violations, annual registration of health physics services in mammography, and annual accreditation or certification fees. These fees are used directly by the mammography program to cover costs.
Items 9, 10, and 14 add wording that refers directly to the current fee schedule in use.
Items 15, 58, and 59 rescind subrules and move them to 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.
Item 16 amends the title because of other items that are being added to the subrule in order to consolidate the enforcement actions.
Items 17 and 18 specify enforcement actions previously stated in an agency policy.
Item 19 adds wording to include both high and low levels. This is in response to pending transportation requirements.
Item 21 corrects the references to reflect current federal code.

Items 22 and 63 move wording from Item 63 to Item 22 for clarification.
Item 23 changes where the device should be worn in accordance with industry standards.
Item 24 adds "or registrant" to include all regulated entities.
Item 25 removes unnecessary wording for clarification.
Item 27 clarifies how long records should be kept.
Item 28 adds new requirements for fluoroscopic equipment. This is the result of documented burns resulting from radiation exposure during medical procedures.
Item 29 amends wording so that all settings used must be checked not just the frequently used ones. This is to improve the quality of checks.
Items 30 and 31 replace wording due to changes in federal requirements.
Item 32 rescinds a grandfathering clause that ended December 31, 1999.
Item 33 requires that individuals in radioactive materials facilities meet the requirements in Chapter 42. This was omitted when the requirements of Chapter 42 went into effect in 1992.
Item 34 adds requirements to allow technologists to become qualified instructors since many technologists do training.
Item 35 changes monitoring frequencies to ensure image quality.
Item 36 corrects a misspelled word.
Items 38, 39, 40, 41, 42, 43, and 44 add the ability to use hours approved by the agency to meet requirements. This allows hours that are not submitted specifically to the AMA to be used to meet requirements.
Item 46 allows monitoring devices that are newer to the industry. It also requires that when monitoring is conducted a second time, the same procedure is followed as the first time.
Item 47 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 48, 49, and 50 change current agency policies into rules as requested by the legislature.
Item 51 moves the training programs requirements to the correct subrule and expands them by adding policies currently in use by the agency.
Item 52 clarifies permit requirements for operators of dual imaging devices, a new device in the industry.
Item 53 deletes clinical requirements that were added in Item 51.
Items 54, 55, and 57 move requirements for clinical experience that were in the wrong subrules.
Item 56 clarifies who may supervise clinical experience.
Items 61, 65, 67, 68, 70, 72, 73 delete a definition moved to another chapter. They also amend wording to reflect the new definition of "direct supervision."
Items 62, 63, 64, 66, 69, 74, 75, and 76 correct the name of the monitoring device. They also change wording to "individual monitoring device" which is more inclusive.
Items 78, 79, and 80 replace current photosensitizing agent lists with a more user-friendly list and place requirements 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.

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

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on February 26, 2001. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa 50309-4611; fax (515)725-0318; or E-mail: dflater@idph.state.ia.us.

A public hearing will be held on February 26, 2001, at 8:30 a.m. in the Conference Room, Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments.

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

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

The following amendments are proposed.

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

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

ITEM 2. Amend rule **641—38.2(136C)** by rescinding the definition of "working level" and "working level month," amending the definition of "major processor" and "written directive," and adding the definitions of "direct supervision" and "high-level radioactive waste," as follows:

"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)~~ 641—38.2(136C) Definitions.

"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 radiopharmaceutial 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:

"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 (HLW)" means: (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**," the first sentence, 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)"c,"~~ 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.

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 S.W. 7th Street, Suite D, Des Moines, Iowa, 50309-4611.

ITEM 6. Amend subrule **38.8(1)**, paragraph "**a**," the first sentence, 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.

ITEM 7. Amend subrule **38.8(1)**, paragraph "**b**," subparagraph **(1)**, by adding **new** bulleted item as follows:

- $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 adding **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 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 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 surbule **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 subrules **38.8(9) and 38.8(10).**

ITEM 16. Amend the title in rule **641—38.9(136C)** 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 adding **new** paragraphs "**c**," "**d**,", "**e**," and "**f**" as follows:
c. Violations are categorized according to five levels of severity, which are:
1. Severity Level 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. 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 it 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. Add **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 is not equipped to observe or 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 written notice to either the owner or the possessor of the source of radiation 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 who 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. Sale, destruction, or other disposition within the agency's discretion.

ITEM 19. Amend subrule **38.8(11)**, paragraph **"a"** as follows:
a. All shippers of high or low level waste containing radioactive materials transporting waste in or across Iowa shall pay the following fee(s) unless the agency is able to obtain appropriate funding from another source (i.e., federal agency).

ITEM 20. 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 21. Amend **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 provision contained in 10 CFR Part 71 ~~as it applies to the state of Iowa.~~ and 49 CFR Parts 170 through 189.

ITEM 22. Amend subrule **40.36(3)** by adding **new** paragraph "**c**" as follows:
c. 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 23. 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 24. Amend subrules **40.90(1)** and **(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 letter, 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 25. Amend subrule **40.112(1), paragraph 1**, 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~~ 641—41.112(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 26. 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 27. Amend subrule **41.1(3)**, paragraph "**c**," by adding the following **new** sentence: 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 28. Amend subrule **41.1(5)** by adding **new** paragraph "**k**" to as follows:
k. Dose-area-product monitor requirements.
(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (i.e. 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 Rads and children (under the age of 18) doses that exceed 100 Rads must be reviewed by the facility's Radiation Safety Committee. The review must document the reason why a dose exceeded 300 Rads for adults or 100 Rads for children and must be documented in the Committee's minutes. If a facility does not have a Radiation Safety Committee, they must provide the agency, within 30 days of the event, with documentation stating why the patient's dose exceeded 300 Rads for adults or 100 Rads 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 29. Amend subrule **41.2(17)**, paragraph "**b**," subparagraph (1) as follows:
(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on ~~frequently~~ used settings with a sealed source of not less than 10 micorcuries (370 kBq) or radium-226 or 50 micorcuries (1.85 MBq) of any other phonton-emitting radionuclide with a half-life greater than 90 days;

ITEM 30. Rescind the current subrule **41.2(31)** and replace it with **new** subrule **41.2(31)** as follows:
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 obtained from a manufacturer or preparer licensed pursuant to 641—39.4(29)"j" or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or 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 641—41.2(11).

ITEM 31. Remove the current subrule **41.2(33)** and replace it with **new** subrule **41.2(33)** as follows:
41.2(33) 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—39.4(29)"j" or equivalent U.S. Nuclear Regulatory Commission or agreement state requirements;
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 641—41.2(11).

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

ITEM 33. Add **new** subrule **41.2(80)** as follows:
41.2(80) Training for nuclear medicine technologists.
(1) Nuclear medicine technologists shall meet the requirements of 641—42.4.
(2) The individual's permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

ITEM 34. Amend subrule **41.6(1)** by amending the 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 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 35. 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 36. 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 37. 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.

ITEM 38. 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 39. 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 40. 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 41. Amend subrule **41.7(3)**, paragraph "**c**," subparagraph **(1)**, numbered paragraph **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"~~ 41.63)"a" and has performed at least 24 stereotactically guided breast biopsies.

ITEM 42. 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 port-biopsy management of the patient.

ITEM 43. Amend subrule **41.7(3)**, paragraph "**d**," subparagraph **(1)**, numbered paragraph **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 44. Amend subrule **41.7(3)**, paragraph "**d**," subparagraph (**2**), numbered paragraph **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 45. Amend subrule **41.7(5)**, paragraph "**a**," as follows:
a. Must be qualified according to ~~41.6(3)"d,"~~ 41.6(3)"b,"

ITEM 46. 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 47. Amend **Chapter 41—Appendix C**, numbered sentence **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 48. Amend subrule **42.2(2)** by adding **new** paragraph "**g**" as follows:
g. Failure to pay fees or costs required to meet the requirements of this chapter.

ITEM 49. Amend subrule **42.2(3)**, paragraph "**b**," by adding **new** subparagraph (**5**) as follows:
(5) No continuing education credit is approved for passing a certification examination.

ITEM 50. 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 51. Rescind subrule **42.2(4)**, paragraph "**d**," and add **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) The body parts to be taught if this is a limited radiography training program.

(2) 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.

(3) 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.

(4) 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 52. Add **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 53. 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 les than twice that required for the original program or course of study.~~

ITEM 54. Amend subrule **42.4(2)** by adding **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 55. 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 56. Amend subrule **42.5(2)** by adding **new** paragraph "**d**" as follows:

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

ITEM 57. 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 radiatin therapy procedure~~.

ITEM 58. Rescind subrule **43.4(6)** and place with **new** subrule **43.4(7)** as follows:

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 measurements 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 either 43.4(7)"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 penaltyi(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 59. Rescind subrule **44.4(6)** and place with **new** subrule **44.4(6)** as follows:
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 641—Chapter 44. 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 larger. 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, it 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 60. 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—Chapter 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 4, 2001~~ May 8, 2002.

ITEM 61. Amend subrule **45.1(2)** by rescinding the definition of "personal supervision" and amending the definition of "radiographer trainee" as follows:
"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 62. 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 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 63. Amend subrule **45.1(12)**, paragraph "**b**," subparagraph **(5), (6), (7),** and **(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 device 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~~ 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 64. 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 65. Amend subrule **45.1(13)** 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.

ITEM 66. 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 67. 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 68. 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 69. 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 according with the appropriate provisions of 641—40.37(136C).

ITEM 70. 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 71. 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 72. Amend subrule **45.6(3)** by rescinding the definition of "personal supervision" and amending the definition of "logging assistant" and "logging supervisor" as follows:
"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 73. 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 74. 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 75. Amend **Chapter 45—Appendix A, II.C.** by adding new numbered sentence **4.** as follows:

4. OSL devices.

ITEM 76. Amend **Chapter 45—Appendix C** as follows:

~~45.3(8)~~45.1(12)	Film badge, OSL devices or TLD records.	Until disposal is authorized by the agency.

ITEM 77. Amend **641—46.1(136D)**, the **second** 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, 2001.

ITEM 78. 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 drigs or agents in the product classes of acne treatment, antibacterials, antibiotics, anticonvulsants, antidepressants, antidiabetics, antihypertensives, dye, estrogen and progesterones, melonogenics, 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 79. Rescind Chapter 46—Appendix 1A and replace with **new** Appendix 1 as follows:

Appendix 1

POTENTIAL PHOTOSENSITIZING 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-Methoxpsoralen, 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, Nortiptyline, Protiptyline), Tranquilizers, anti-emetics (Phenothiazines)

Antidiabetic (glucose-lowering agents) (sulfonylureas, oral anti-diabetics, 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 ("water-pills")

ITEM 80. Rescind Chapter 46—Appendix 1B and 1C.

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Stephen C. Gleason, Director Date