

PUBLIC HEALTH DEPARTMENT [641]
Adopted and Filed

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

The following itemize the proposed changes.

Items 1, 4, 7, 12, 22, 37, and 52 amend the rules to reflect current federal regulations.

Items 2 and 23 amend the definitions to meet NRC compatibility requirements.

Item 3 adds an inspection fee for mammography units not covered under the current inspection fee schedule.

Items 5, 8, 10, 14, 17, 18, 19, 24, 48, and 49 correct and clarify terminology.

Item 6 adds requirements for a well logging license to meet NRC compatibility requirements.

Item 9 adds wording to eliminate the requirement for certain X-ray rooms to be posted with caution signs in order to meet national standards.

Items 11, 28, 29, and 30 add language to address new technology.

Item 13 corrects wording from a previous amendment which was not submitted correctly.

Item 15 rescinds a subparagraph whose substance has been appropriately incorporated elsewhere.

Item 16 adds a time requirement for maintaining records, removes items that are no longer necessary because of new technology, and renumbers the subparagraphs.

Item 20 changes wording to require that the patient's physician do a follow-up instead of the surgeon who may not see the patient on a regular basis.

Item 21 incorporates language appropriate to the rule and expands it for clarity.

Items 25, 26, 27, and 42 amend the rules to meet NRC compatibility requirements.

Item 31 adds language to allow probation for disciplinary actions.

Item 32 expands the criteria for disciplinary actions to include all modalities in the chapter.

Item 33 adds a penalty for working without a permit issued under Chapter 42. The purpose of the penalty is to encourage new graduates to get the permit before they start working as is currently required.

Item 34 adds a new category for disciplinary actions because of the increase in the number of individuals who are not submitting proper documentation.

Item 35 adopts new language for limited radiographers who wish to be trained in pediatric radiography. This change was recommended by many doctors.

Item 36 clarifies that the required test is for the general radiography category.

Item 38 corrects references.

Items 39, 45, 47, and 51 change the number of years that records must be maintained in order to meet NRC compatibility requirements.

Items 40 and 44 delete language referring to forms the agency no longer issues.

Items 41, 43, and 50 rescind the original paragraphs and replace them with revised paragraphs to meet NRC compatibility requirements.

Item 46 adopts a new subrule to meet NRC compatibility requirements.

Item 53 adopts new requirements for tanning facility operators. The first paragraph will affect operators of in-home tanning facilities. The second will require training every five years instead of the current one-time training. This change should create a good periodic review of the rules for operators.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on February 4, 2004 as **ARC 3147B**. A public hearing was held on February 24, 2004. No person attended the hearing. Three sets of written comments were received, reviewed, and incorporated as appropriate. The changes made from the Notice of Intended Action are listed below.

1. In Item 13, the phrase, "A verbal order may be issued provided the licensed practitioner is directly supervising the procedure and the order is documented in the patient's record after the procedure is completed," was added to allow flexibility during healing arts procedures.

2. In Item 17, the phrases, "Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation," were added to allow justified deviations for special procedures or situations where no manufacturer's recommendations are available.

3. In Item 45, the phrase, "until the agency authorizes disposal" was replaced with, "for three years after they are recorded." This change is an NRC compatibility recommendation.

4. In Item 51, the phrase "45.3(4) Leak tests," was corrected to read, "45.3(5) Leak tests." The time interval for 45.1(7) Utilization logs was changed from "until disposal is authorized by the agency" to "3 years." The time interval for 45.1(10) Training and testing records was changed from "until disposal is authorized by the agency" to "3 years." The time interval for 45.1(12) Pocket dosimeter readings was changed to delete all the wording except "3 years." The time interval for 45.1(19) Current operating and emergency procedures was changed from "until disposal is authorized by the agency" to "until the license is terminated." These changes are NRC compatibility recommendations.

The State Board of Health adopted these amendments on March 10, 2004.

The Amendments will become effective May 5, 2004.

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

The following amendments are adopted.

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

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 1, 2003~~ May 5, 2004.

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

Amend the following definitions:

“A2” means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are ~~either listed in Appendix E of 641—Chapter 39, Table I, or may be derived in accordance with the procedure prescribed in Appendix E of 641—Chapter 39~~ 49 CFR 173.435.

“Brachytherapy” means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

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

Add the following **new** definitions in alphabetical order as follows:

"Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

"Diagnostic imaging system" means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

"High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

"Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 200 rads (2 gray) per hour at the point or surface where the dose is prescribed.

"Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

"Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

ITEM 3. Amend subrule **38.8(1)**, paragraph "b," subparagraph (1), by adopting the following **new** bulleted paragraph as follows:

- \$850 for each stereotactic breast biopsy unit.

ITEM 4. Amend subrule **39.1(3)** as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 1, 2003~~ May 5, 2004.

ITEM 5. Amend subrule **39.4(29)**, paragraph "j," introductory paragraph, as follows:

j. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing by-product material for ~~material~~ medical use under 641—41.2(136C).

ITEM 6. Amend subrule **39.4(31)** by adopting **new** paragraph "d" as follows:

d. Specific licenses for well logging. The agency will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements:

(1) The applicant shall satisfy the general requirements specified in 39.4(25) and all other requirements in 641—Chapter 39, as appropriate, and any special requirements contained in 39.4(31)"d."

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the agency a description of this program which specifies the following:

1. Initial training;
2. On-the-job training;
3. Annual safety reviews provided by the licensee;
4. The means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the agency's regulations and licensing requirements and the applicant's operating and emergency procedures; and
5. The means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

(3) The applicant shall submit to the agency written operating and emergency procedures as described in 641—subrule 45.6(16) or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the agency its program for annual inspections of the job performance of each logging supervisor to ensure that the agency's regulations and license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as the organizational structure applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the agency. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

ITEM 7. Amend subrule 40.1(5) as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before ~~May 1, 2003~~ May 5, 2004.

ITEM 8. Amend subrule **40.60(4)** as follows:

40.60(4) ~~Deceptive Improper~~ posting or labeling. The licensee or registrant shall ensure that adequate measures are taken to prevent ~~deceptive improper~~ posting or labeling.

ITEM 9. Amend subrule **40.62(4)** as follows:

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis or simulation in the healing arts.

ITEM 10. Amend **641—Chapter 40**, Appendix D, title, as follows:

CHAPTER 40
APPENDIX D
REQUIREMENTS FOR TRANSFERS AND MANIFESTS OF LOW-LEVEL RADIOACTIVE
WASTE
INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND
MANIFESTS

ITEM 11. Amend subrule **41.1(1)**, introductory paragraph, as follows:

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems 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.

ITEM 12. Amend subrule **41.1(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 1, 2003~~ May 5, 2004.

ITEM 13. Amend subrule **41.1(3)**, paragraph "a," subparagraph (7), introductory paragraph, as follows:

(7) Individuals shall not be exposed to the useful beam unless (1) ~~there is a previously established professional relationship with the radiation exposure occurs in the context of a previously established professional relationship between a~~ licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless it is such examination is not otherwise clinically appropriate indicated; and (2) ~~a written order for the radiation exposure has been issued by the individual in~~ (4) such practitioner issues a written order for the radiation exposure. The written order ~~may be issued after the exposure that is the result of~~ shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is directly supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

ITEM 14. Amend subrule 41.1(3), paragraph "a," subparagraph (9), numbered paragraph "5," the second bulleted paragraph, as follows:

- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

ITEM 15. Rescind subrule **41.1(3)**, paragraph "a," subparagraph (12).

ITEM 16. Amend subrule **41.1(3)**, paragraph "b," as follows:

b. Information and maintenance record and associated information. Records in 41.1(3)"b"(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)"b"(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) ~~Model and serial numbers of all major components and user's~~ User's manual for ~~those components~~ the X-ray system;

(2) ~~Tube rating charts and cooling curves~~;

(3) (2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(4) (3) A copy of all correspondence with this agency regarding that X-ray system.

ITEM 17. Amend subrule **41.1(3)**, paragraph "f," subparagraph (1), numbered paragraph "2," as follows:

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's

recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

ITEM 18. Amend subrule **41.1(3)**, paragraph "f," subparagraph (2), numbered paragraph "1," as follows:

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

ITEM 19. Amend subrule **41.1(5)**, paragraph "a," subparagraph (2), numbered paragraph "2," as follows:

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the ~~minimum~~ maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

ITEM 20. Amend subrule **41.1(5)**, paragraph "k," subparagraph (2), as follows:

(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 patient's 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.

ITEM 21. Amend subrule **41.1(5)** by adopting new paragraph "l" as follows:

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) The use of fluoroscopic X-ray systems by radiologic technologists and students shall be performed under the direct supervision of a licensed practitioner of the healing arts for the purpose of localization to obtain images for diagnostic purposes.

(3) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(4) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

ITEM 22. Amend subrule **41.2(1)**, paragraph "b," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 1, 2003~~ May 5, 2004.

ITEM 23. Amend subrule **41.2(2)** as follows:

Amend the following definition:

"Authorized nuclear pharmacist" means a pharmacist who has met the appropriate requirements of 41.2(77) and 41.2(78) and who:

- a. Is practicing nuclear pharmacy as authorized by a current Iowa radioactive materials license; or
- b. Is identified as an authorized nuclear pharmacist on:
 - 1. A specific license issued by the NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;
 - 2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - 3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes ~~more than~~ medical use or the practice of nuclear pharmacy; or
 - 4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
- c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
- d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29)“j”(2)“3.”

ITEM 24. Amend subrule **41.2(14)**, paragraph "a," as follows:

a. When a misadministration or reportable medical event (as defined in 641—38.2(136C)) occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient’s or human research subject’s responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration or reportable medical event. If the referring physician, patient or human research subject, or the patient’s or human research subject’s responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient’s or human research subject’s responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the misadministration or reportable medical event because of any delay in notification.

ITEM 25. Amend subrule **41.2(69)** as follows:

41.2(69) Training for therapeutic use of radiopharmaceuticals.

a. The licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for therapy to be a physician who:

~~a.~~(1) Is certified by:

~~(1)~~1. The American Board of Nuclear Medicine; or

~~(2)~~2. The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

~~(3)~~3. ~~Nuclear medicine by the~~ The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

~~(4)~~4. The American Osteopathic Board of Radiology after 1984; or

~~b.~~(2) ~~Has completed 80 hours of instruction~~ had classroom and laboratory training in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience: as follows:

~~(1)1.~~ To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include that includes:

- ~~1.~~ Radiation physics and instrumentation;
- ~~2.~~ Radiation protection;
- ~~3.~~ Mathematics pertaining to the use and measurement of radioactivity; and
- ~~4.~~ Radiation biology; and

~~(2)2.~~ To satisfy the requirement for supervised clinical experience, training shall be Supervised clinical experience under the supervision of an authorized user at a medical institution and shall include:

- ~~1.~~ Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;
- ~~2.~~ Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;
- ~~3.~~ Use of iodine-131 for treatment of thyroid carcinoma in three individuals;
- ~~4.~~ Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals;
- ~~5.~~ Use of strontium-89 or samarium-153 for relief of pain in metastatic disease in three individuals; and
- ~~6.~~ Use of iodine-131 radiolabeled monoclonal antibody for treatment of non-Hodgkin's lymphoma in three patients; or,

~~e. Be identified on a current Agreement State or NRC license as an authorized user for these uses in 41.2(37).~~

b. Training for the treatment of hyperthyroidism. Except as provided in 41.2(37), the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism in ten individuals.

c. Training for treatment of thyroid carcinoma. Except as provided in 41.2(37), the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in three individuals.

ITEM 26. Amend subrule **41.2(73)** as follows:

41.2(73) Training for ~~teletherapy~~ use of therapeutic medical devices. The licensee shall require the authorized user of a sealed source specified in 41.2(49) ~~in a teletherapy unit~~ to be a physician who:

a. Is certified in:

- (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
- (2) Radiation oncology by the American Osteopathic Board of Radiology;
- (3) Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
- (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has ~~completed 200 hours of instruction~~ classroom and laboratory training in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit therapeutic medical device, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience. as follows:

(1) ~~To satisfy the requirement for instruction, the 200 hours of classroom and laboratory training shall to include:~~

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; ~~;~~ and

(2) ~~To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an a medical institution and shall include:~~

1. Review of the full calibration measurements and periodic spot checks;
2. Preparing treatment plans and calculating treatment times;
3. Using administrative controls to prevent ~~misadministrations~~ medical events;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of a ~~teletherapy unit~~ medical device or console; and
5. Checking and using survey meters; ~~;~~ and

(3) ~~To satisfy the requirement for a period Three years of supervised clinical experience, training shall include that includes~~ one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. ~~The supervised clinical experience shall include that includes:~~

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment and any limitations or contraindications;
2. Selecting the proper dose and how it is to be administered;
3. Calculating the ~~teletherapy~~ doses and collaborating with the authorized user in the review of patients’ or human research subjects’ progress and consideration of the need to modify originally prescribed doses as warranted by patients’ or human research subjects’ reaction to radiation; and

4. Postadministration follow-up and review of case histories;
e. ~~Be identified on a current Agreement State or NRC license as an authorized user for teletherapy.~~

ITEM 27. Amend subrule **41.2(74)** as follows:

41.2(74) Training for ~~teletherapy~~ authorized medical physicist. The licensee shall require the ~~teletherapy~~ authorized medical physicist to:

a. Be certified by:

(1) The American Board of Radiology in:

1. Therapeutic radiological physics;
2. Roentgen-ray and gamma-ray physics;
3. X-ray and radium physics; or
4. Radiological physics; or

~~5.(2) The American Board of Medical Physics in radiation oncology physics; or~~

~~(2) Reserved; or~~

b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and ~~also~~ one additional year of full-time work experience under the supervision of a ~~teletherapy~~medical physicist at a medical institution. ~~To meet this requirement, the individual shall have performed that includes the tasks listed in 41.2(21), 41.2(58), 41.2(59), and 41.2(60) under the supervision of a teletherapy physicist during the year of work experience, as applicable.~~

~~e. Be identified on a current Agreement State or NRC license as a teletherapy physicist.~~

ITEM 28. Amend subrule **41.6(1)** by adopting the following new definition in alphabetical order:

"Image receptor support device" means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

ITEM 29. Amend subrule **41.6(3)**, paragraph "a," subparagraph (2), numbered paragraph "3," as follows:

3. Before an interpreting physician may begin independently interpreting mammograms produced by a new screen-film or full field digital mammographic modality modalities, ~~that is, a mammographic modality in which the physician has not previously been trained~~, the interpreting physician shall have at least 8 hours of training category 1 continuing medical education credits in the new mammographic modality. An interpreting physician who has previously qualified to interpret digital mammography in another state will have six months to complete this requirement. The six-month time frame starts when the interpreting physician commences Iowa digital mammography interpretation.

ITEM 30. Amend subrule **41.6(3)**, paragraph "b," subparagraph (2), numbered paragraphs "1" and "3," as follows:

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

3. At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography examinations. The 8 hours shall not include hours derived from performance of supervised examinations; and

ITEM 31. Amend subrule **42.2(2)**, introductory paragraph, as follows:

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

ITEM 32. Amend subrule **42.2(2)**, paragraph "e," subparagraphs (1) and (3), as follows:

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

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

ITEM 33. Amend subrule **42.2(2)**, paragraph "g," as follows:

g. Failing to pay fees or costs required to meet the requirements of this chapter. The penalty for working without the required permit will be \$100 and suspension from performing radiography until the permit is issued.

ITEM 34. Amend subrule **42.2(2)** by adopting new paragraph "h" as follows:

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

ITEM 35. Amend subrule **42.3(1)**, paragraph "b," by adopting new subparagraph (2) as follows:

(2) Training required for limited radiographers who wish to perform pediatric radiography. The training program must:

1. Be submitted to the agency for approval before training starts.

2. Be taught by a general radiographer.

3. Include 4.0 hours of additional anatomy and physiology, positioning, radiation protection, and technique that are specific to pediatric radiography.

4. Include clinical and film critiques in pediatric chest and extremities radiography, but no spinal radiography

5. Upon completion, verify each participant's competency, in writing, to the agency.

ITEM 36. Amend subrule **42.3(3)**, paragraph "c," as follows:

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

ITEM 37. Amend subrule **45.1(1)**, paragraph "b," introductory paragraph, as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 1, 2003~~ May 5, 2004.

ITEM 38. Amend subrule **45.1(2)**, definitions of "certifying entity" and "independent certifying organization," as follows:

"Certifying entity" means an independent certifying organization meeting the requirements in ~~Appendix E of this chapter or Agreement State meeting the requirements of Appendix E or the requirements~~ of Appendix A in 10 CFR Part 34.

"Independent certifying organization" means an independent organization that meets all of the criteria of ~~Appendix E to this chapter~~ Appendix A in 10 CFR Part 34.

ITEM 39. Amend subrule **45.1(6)** as follows:

45.1(6) Quarterly inventory. Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for ~~two~~ three years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

ITEM 40. Amend subrule **45.1(7)**, paragraph "c," as follows:

c. Utilization logs may be kept on ~~IDPH Form 588-2693, Utilization Log, or on~~ clear, legible records containing all the information required by 45.1(7)"a" or "b." Copies of utilization logs shall be maintained for agency inspection for three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

ITEM 41. Amend subrule **45.1(8)** by rescinding paragraphs "a" and "c" and adopting the following new paragraphs in lieu thereof:

a. Each licensee or registrant shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means.

c. Each licensee shall have a program and written procedures for the inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The program must include procedures to ensure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

ITEM 42. Amend subrule **45.1(8)**, paragraph "b," as follows:

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

ITEM 43. Amend subrule **45.1(8)** by adopting new paragraphs "d" and "e" as follows:

d. If equipment problems are found, the equipment must be removed from service until repaired.

e. The record of equipment problems and of any maintenance performed under 45.1(8) must be retained for three years after the record is made. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair or maintenance, if any, was performed.

ITEM 44. Amend subrule **45.1(10)**, paragraph "e," as follows:

e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10)“a” and “b” are met for all industrial radiographic personnel. ~~Records shall be kept on IDPH Form 588-2692 or on clear, legible records containing all the information required by IDPH Form 588-2692.~~ Records shall be maintained until disposal is authorized by the agency. The agency shall not release records for disposal unless the records have been maintained at least three years.

ITEM 45. Amend subrule **45.1(12)**, paragraph "c," as follows:

c. Records of pocket dosimeter readings of personnel exposures and yearly operability checks required in 45.1(12)“d” shall be maintained for ~~two~~ three years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained ~~until the agency authorizes disposal~~ for three years after they are recorded. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges, OSLs, or TLDs, shall be maintained until the agency terminates the license.

ITEM 46. Adopt new subrule **45.1(19)** as follows:

45.1(19) Copies of operating and emergency procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the agency terminates the license. Superseded material must be retained for three years after the change is made.

ITEM 47. Amend subrule **45.3(5)**, paragraph "c," as follows:

c. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 641—subparagraph 39.4(27)“e”(5). Records of leak test results shall be kept in units of microcuries (becquerels) and maintained for inspection by the agency for ~~six months~~ three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

ITEM 48. Amend subrule **45.6(9)**, paragraph "e," subparagraph (5), as follows:

(5) Sources of alpha- or neutron-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

ITEM 49. Amend subrule **45.6(15)**, paragraph "a," subparagraph (1), as follows:

(1) Received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Appendix ~~D~~ E of this chapter and demonstrated an understanding thereof;

ITEM 50. Rescind subrule **45.6(16)** and adopt the following new subrule in lieu thereof:

45.6(16) Operating and emergency procedures. Each licensee or registrant shall develop and follow written operating and emergency procedures that cover:

- a. The handling and use of sources of radiation including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;
- b. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

- c. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 45.6(22);
- d. Minimizing personnel exposure, including exposures from inhalation and ingestion of licensed tracer materials;
- e. Methods and occasions for locking and securing stored licensed or registered materials;
- f. Personnel monitoring and the use of personnel monitoring equipment;
- g. Transportation of licensed or registered materials to field stations or temporary job sites, packaging of licensed or registered materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;
- h. Picking up, receiving, and opening packages containing licensed or registered materials, in accordance with 641—40.65(136C);
- i. For the use of tracers, decontamination of the environment, equipment, and personnel;
- j. Maintenance of records generated by welllogging personnel at temporary job sites;
- k. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 45.6(14);
 - l. Identifying and reporting defects and noncompliance;
 - m. Actions to be taken if a sealed source is lodged in a well;
 - n. Notifying proper persons in the event of an accident; and
 - o. Actions to be taken if a sealed source is ruptured that include actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required in 45.6(8).

ITEM 51. Amend **641—Chapter 45**, Appendix C, as follows:

**CHAPTER 45—APPENDIX C
TIME REQUIREMENTS FOR RECORD KEEPING**

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(4)	Receipt, transfer and disposal.	Until disposal is authorized by the agency.
45.1(5)	Survey instrument calibrations.	2 <u>3</u> years.
45.3(4) 45.3(5)	Leak tests.	2 <u>3</u> years.
45.1(6)	Quarterly inventory.	2 <u>3</u> years.
45.1(7)	Utilization logs.	Until disposal is authorized by the agency. <u>3</u> years.

45.1(8)	Quarterly inspection and maintenance.	2 <u>3</u> years.
45.1(9)	High radiation area control devices or alarm systems.	Until disposal is authorized by the agency.
45.1(10)	Training and testing records.	Until disposal is authorized by the agency. <u>3 years.</u>
45.1(12)	Pocket dosimeter readings.	2 <u>3</u> years or until disposal is authorized by the agency if dosimeters were used to determine external radiation dose.
	Pocket dosimeter calibrations.	2 years.
	Film badge, OSL device, or TLD reports.	Until disposal is authorized by the agency.
	Alarming ratemeter calibrations.	2 years.
	Alarming ratemeter functions.	2 years.
<u>45.1(19)</u>	<u>Current operating and emergency procedures</u>	<u>Until the license is terminated.</u>
	<u>Superseded material</u>	<u>3 years after change.</u>
45.3(6) <u>40.81(1)</u>	Internal audit program.	3 years.
<u>45.1(11)</u>	Radiographer audits.	2 <u>3</u> years.
45.2(5) and 45.3(7)	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine an individual's exposure.
45.1(16)	Records at temporary job sites.	During temporary job site operations.
45.2(6) and 45.3(8)	Annual evaluation of enclosed	

X-ray systems. 2 years.

45.1(9) Tests of Chapter 45 high radiation control devices and alarm systems. Until disposal is authorized by the agency.

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

ITEM 52. 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 ~~July 1, 2002~~ May 5, 2004.

ITEM 53. Amend subrule **46.5(10)** by adopting new paragraphs "e" and "f" as follows:

- e. Operators shall be at least 16 years of age.
- f. Operators shall complete the required training and testing every five years.

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

Date