

5912BPUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby 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 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 paragraphs itemize the adopted changes:

The following paragraphs itemize the proposed changes.

Item 1 increases fees for registering generally licensed radioactive materials. The agency is tasked with charging fees necessary to cover the cost of operation.

Item 2 increases fees for the industrial radiography examination given by the agency. The fee charged by the company providing the examination was increased.

Item 3 corrects language to cover all entities possessing radioactive materials or machines that might need surveillance activities.

Item 4 adds fees for podiatry assistants. This program has been transferred from the Podiatry Board to the Bureau of Radiological Health.

Item 5 ties the training requirements for radiation therapy physicists to the fees for providing services.

Item 6 places restrictions on operators of CT equipment that have been agency standards for some time.

Item 7 adds a definition required to meet Nuclear Regulatory Commission compatibility.

Items 8, 14, and 17 rescind a subrule that is no longer in effect.

Items 9, 12, 13, 15, 16, and 18 correct references.

Items 10 and 11 change language in order to meet Nuclear Regulatory Commission compatibility.

Items 19, 20, 21, 26, 27, 28, and 35 add language for podiatry assistants. This program has been transferred from the Podiatry Board to the Bureau of Radiological Health.

Items 22, 23, 24, 31, and 32 add language for certification of operators of CT units. This is a new area of regulation.

Items 25, 29, 30, 33, and 34 correct and clarify language for training of operators in diagnostic radiography, nuclear medicine, and radiation therapy.

Item 36 add language to clarify who is qualified as a trainer of industrial radiographers.

Item 37 clarifies the process for registering a tanning facility.

Item 38 adds information about the different types of tanning units to the information that all tanning customers are required to read. This information is to clarify the difference between the tanning units.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on June 6, 2007, as **ARC 5912B**. A public hearing was held on June 26, 2007. Three individuals attended the hearing and presented two sets of verbal comments. Seven sets of written comments were received and reviewed, and changes were incorporated as appropriate. The changes made from the Notice of Intended Action are as follows:

1. In Item 19, the words, "but not CT or fluoroscopy" were added to the definition of "Podiatry assistant." Podiatry assistants are not allowed to perform CT or fluoroscopic studies.
2. In Item 21, the words, "podiatric radiographer," were changed to read, "podiatric assistant." These words are consistent with the rest of the rules.
3. In Item 33, wording was added and changed so that the wording added reads, "Clinical experience for each area must be directly supervised by a formally educated general radiographer until competency for the area is completed. After competency is completed, indirect supervision is permitted. All retakes and portable radiography must be directly supervised." The additional wording was omitted from the noticed amendment.
4. In Item 35, the wording in 42.7(1)"a"(2) the first paragraph was changed from "include equipment maintenance, exposures and positioning, film processing, film evaluation for quality, and mounting and filing of radiographic films," to "include equipment maintenance, exposures and positioning, image processing, image evaluation for quality, and display and storage of radiographic images." The change uses updated language.

The State Board of Health adopted these amendments on July 11, 2007.

These amendments become effective September 19, 2007.

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

The following amendments are adopted.

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

c. Registration. Each person having generally licensed radioactive materials shall annually register with the department and pay a nonrefundable annual fee of ~~\$150~~ \$200.

ITEM 2. Amend subrule **38.8(3)**, paragraph "a," as follows:

a. A nonrefundable fee of ~~\$150~~ \$175 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

ITEM 3. Amend subrule **38.8(5)**, as follows:

38.8(5) Environmental surveillance fee. A fee may be levied against any licensee, registrant, corporation, company, business, or individual for environmental surveillance activities which are necessary to ~~access~~ assess the radiological impact of activities conducted by the licensee, registrant, corporation, company, business, or individual. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

ITEM 4. Amend subrule **38.8(6)**, introductory paragraph, as follows:

38.8(6) Certification fees. Diagnostic radiographers, radiologist assistants, radiation therapists, and nuclear medicine technologists (as defined in 641—Chapter 42), other than licensed practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering 641—Chapter 42. For podiatry assistants' fees, see 641—42.7(136C). Fees are as follows:

ITEM 5. Amend subrule **39.3(3)**, by adopting **new** paragraph "g," as follows:

g. Radiation therapy physicists providing services for therapeutic radiation machines must provide proof that the training requirements of 41.3(6) have been met.

ITEM 6. Amend subrule **41.1(11)**, paragraph "d," subparagraph (4), the first numbered paragraph, as follows:

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation in accordance with 641—42.2(9).

ITEM 7. Amend subrule **41.2(2)**, definitions, by adopting **new** definition in order:

"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

ITEM 8. Rescind and reserve subrule 41.2(18), paragraph "g."

ITEM 9. Amend subrule **41.2(59)**, paragraph "a," subparagraph (7), as follows:

(7) A licensee shall retain a copy of the procedures required by ~~41.2(59)"b"~~ 41.2(59)"a"(2) until the licensee no longer possesses the teletherapy unit.

ITEM 10. Amend subrule **41.2(59)**, paragraph "b," subparagraph (6), as follows:

(6) A licensee shall retain a record for three years of each spot check required in 41.2(59)"b"(4) ~~and a copy of the procedures required by 41.2(59)"b"(2)~~. The record must include:

ITEM 11. Amend subrule **41.2(59)**, paragraph "c," subparagraph (7), as follows:

(7) A licensee shall retain a record for three years of each spot check required by 41.2(59)"c"(3) and (4) ~~and a copy of the procedures required in 41.2(59)"c"(2)~~. The record must include:

ITEM 12. Amend subrule **41.2(65)**, the introductory paragraph, as follows:

41.2(65) Training for radiation safety officer. Except as provided in ~~41.2(66)~~ 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) to be an individual who:

ITEM 13. Amend subrule **41.2(68)**, the introductory paragraph, as follows:

41.2(68) Training for imaging and localization studies. Except as provided in ~~41.2(76)~~ 41.2(75), the licensee shall require the authorized user of unsealed radioactive material specified in 41.2(33) to be a physician who:

ITEM 14. Rescind and reserve subrule 41.2(76).

ITEM 15. Amend subrule **41.2(77)**, as follows:

41.2(77) Recentness of training. The training and experience specified in 41.2(65) to ~~41.2(79)~~ 41.2(78) and 41.2(81), 41.2(82), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

ITEM 16. Amend subrule **41.2(78)**, the introductory paragraph, as follows:

41.2(78) Training for an authorized nuclear pharmacist. Except as provided in ~~41.2(79)~~ 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

ITEM 17. Rescind and reserve subrule 41.2(79).

ITEM 18. Amend subrule **41.3(17)**, paragraph "b," introductory paragraph, as follows:

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of ~~41.3(8)~~ 41.3(19), the treatment room shall meet the following design requirements:

ITEM 19. Amend subrule **42.1(2)** definitions as follows:

Amend the following definitions:

"Clinical education" means the direct participation of the student in ~~completion of diagnostic studies~~ radiographic exposures as part of the approved course of study.

"Radiation therapy technology" means the science and art of performing simulation radiography or applying ionizing radiation emitted from X-ray machines, particle accelerators, or radioactive materials in the form of sealed sources to human beings for therapeutic purposes.

Adopt **new** definitions in alphabetical sequence:

"ARRT" means the American Registry of Radiologic Technologists.

"Clinical podiatric sponsor" means a person licensed under Iowa Code chapter 149 and supervising the podiatric student.

"Podiatric radiography" means the application of x-radiation to the human foot and ankle for diagnostic purposes only.

"Podiatry assistant" means an individual employed in a podiatry office who performs podiatric radiography but not CT or fluoroscopy.

ITEM 20. Amend subrule **42.2(1)**, by adopting new paragraph "j":

j. Podiatry assistants shall follow the application process in 641—42.7(4)(136C).

ITEM 21. Amend subrule **42.2(2)**, paragraphs "a," "b," and "d," as follows:

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

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

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

ITEM 22. Amend subrule **42.2(3)**, paragraph "a," subparagraph (1), as follows:

(1) General diagnostic radiographer: 24 clock hours, 1.0 hour must be in radiation protection. Subjects must be directly related to general diagnostic radiography as defined in 42.1(2) and approved by the agency.

1. Individuals holding an additional category in CT as specified in 42.2(9), must complete 6.0 of the 24.0 hours in CT related courses.

2. Individuals not holding the additional category in CT may not submit continuing education hours in CT.

ITEM 23. Amend subrule **42.2(3)**, paragraph "a," subparagraph (4), numbered paragraph **3**. as follows:

3. The remaining 20 clock hours of continuing education in each two-year period ~~may~~ must be in ~~any other~~ subjects related to nuclear medicine procedures as defined in 42.1(2) and approved by the department agency.

1. Individuals holding an addition category in CT as specified in 42.2(9), must complete 6.0 of the 24.0 hours in CT related courses.

2. Individuals not holding the additional category in CT may not submit continuing education hours in CT.

ITEM 24. Amend subrule **42.2(3)**, paragraph "a," subparagraph (6), as follows:

(6) Radiation therapist, dosimetrist, simulation therapist: ~~proof of 24.0 clock hours, 1.0 hour must be in radiation protection. -of e~~Continuing education courses ~~in subjects~~ must be directly related to radiation therapy as defined in 42.1(2) and approved by the agency.

1. Individuals holding an additional category in CT must complete 6.0 of the 24.0 hours in CT related courses.

2. Individuals not holding an additional category in CT may not submit continuing education hours in CT.

ITEM 25. Rescind and reserve subrule 42.2(3), paragraph "a", subparagraph (7).

ITEM 26. Amend subrule **42.2(3)**, paragraph "a," by adopting **new** subparagraph (10):

(10) Podiatry assistant: See 42.7(5).

ITEM 27. Amend subrule **42.2(3)**, paragraph "g," subparagraph (2), as follows:

(2) Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours plus 3.0 additional penalty hours for limited technologists and 6.0 additional hours for general technologists and 1.0 hour for podiatric assistants and the fee required in 38.8(6)"c" shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and additional penalty hours and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist or as a podiatric radiographer in Iowa.

ITEM 28. Amend subrule **42.2(4)**, paragraph "a," by adopting **new** subparagraph (4):

(4) Podiatry assistants see 641—42.7(6)(136C).

ITEM 29. Amend subrule **42.2(6)**, paragraph "a," subparagraph (3) as follows:

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

ITEM 30. Amend subrule **42.2(6)**, paragraph "a," by adopting **new** subparagraph (6):

(6) A statement of permission to allow a representative of the agency to periodically evaluate the progress of the student.

ITEM 31. Amend subrule **42.2(7)**, as follows:

42.2(7) Requirements for operators of dual imaging devices.

a. When a unit is operated as a stand-alone nuclear medicine imaging device, the operator must have a permit to practice as a nuclear medicine technologist and meet the requirements of 641—42.4(136C).

b. When the unit is operated as a stand-alone CT imaging device, the operator must have a permit to practice as a general diagnostic radiographer, nuclear medicine technologist, or radiation therapist and meet the requirements of 641—42.3(136C) 42.2(9).

c. When a unit is operated in dual mode as a SPECT/CT or PET/CT device, the operator must have a permit to practice as a nuclear medicine technologist and meet the requirements of 42.2(9).

~~b. In order to operate a SPECT/CT or PET/CT unit as a stand-alone CT unit, the individual must:~~

~~(1) Be certified as a nuclear medicine technologist;~~

~~(2) Complete a training program approved by the agency; and~~

~~(3) Successfully complete the ARRT specialty examination for CT.~~

ITEM 32. Adopt **new** subrule **42.2(9)** as follows:

42.2(9) Specific requirements for CT certification.

a. Operators of CT units must meet the following requirements:

(1) Hold certification as a general diagnostic radiographer, radiation therapist, or nuclear medicine technologist;

(2) Complete the manufacturer's training or an agency approved equivalent training course. Training must include equipment operation, contrast media, sectional anatomy, and CT radiation protection and be at least 15.0 hours in length. Initial training may be used as continuing education in the reporting period taken if approved by the agency. Passing the ARRT certification examination in CT will meet the training requirement.

(3) Complete 6.0 hours of continuing education in CT related subjects each two-year reporting period. These hours may be a part of the 24.0 hours of continuing education required in 42.2(3)"a"(1), (4), and (6).

b. Proof of initial training shall be forwarded to the agency for review.

c. "CT" must be on the individual's permit in order for the individual to perform CT scans.

ITEM 33. Amend subrule **42.3(1)**, paragraph "a," subparagraph (7), as follows:

(7) Clinical experience sufficient to demonstrate competency in the application of the above as specified in the "Standards for an Accredited Education Program in Radiologic Sciences" as adopted by the Joint Review Committee on Education on Radiologic Technology. Clinical experience must be directly supervised by a formally trained general radiographer until competency for the area is completed. After competency is completed, indirect supervision is permitted. All retakes and portable radiography must be directly supervised.

ITEM 34. Rescind and reserve subrule 42.3(1), paragraph "b," subparagraph (1), the eighth numbered paragraph.

ITEM 35. Adopt new rule **641—42.7(136C)** as follows:

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

42.7(1) Training requirements. Any person wishing to operate radiation-emitting equipment for purposes of podiatric radiography shall:

a. Complete an approved program or course of study that includes the following:

(1) Didactic training in podiatric radiological practices including radiation health, safety, and physics, lower extremity anatomy and physiology, positioning techniques, infection control, equipment maintenance with efficiencies to minimize radiation exposure and frequency of retakes. The didactic training shall be at least 15 hours in length, and,

(2) A radiographic clinical program sufficient to demonstrate proficiency to a podiatric sponsor. Training shall:

1. Include equipment maintenance, exposures and positioning, image processing, image evaluation for quality, and display and storage of radiographic images.

2. Include at least 50 total exposures. Exposures must be taken in at least 20 working days in a podiatric office or clinic.

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

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

(3) Upon completion of the training in 42.7(1)"a," submit a form signed by the clinical podiatric sponsor certifying completion of and competency of 42.7(1)"a"(2); and

b. Pass a written examination approved by this agency; or

c. Meet the requirements of this rule after submission of proof that the individual holds a current certificate in podiatric radiography issued by another state, jurisdiction, agency or recognized professional registry provided that the agency finds that the standards, procedures, and examinations are equivalent to 641—42.7(136C).

42.7(2) Examination.

a. Examination will be given by an agency approved entity and proctored by appropriate personnel.

b. Passing score is 70 percent or greater.

c. Any individual who fails the examination in three tries must successfully repeat the didactic portion of the training program before testing again.

42.7(3) Exemptions.

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

b. Licensed practitioners as defined in 641—Chapter 38.

42.7(4) Application for certification. Any individual seeking certification under 641—42.7 shall:

a. Graduate from high school or its equivalent;

b. Be at least 18 years of age;

c. Be able to adequately perform necessary duties without constituting a hazard to the health and safety of patients or operators;

d. Satisfactorily complete the agency approved didactic and clinical training;

- e. Satisfactorily complete the agency approved examination;
- f. Upon completion of "d" and "e", apply to the agency for a permit to practice and pay a fee of \$25;
- g. Submit an annual renewal application that includes the \$25 fee;
- h. Submit copies of proof of completion of continuing education required in subrule 42.7(5);
- i. Post the permit at the individual's place of employment;
- j. Work only under the supervision of a licensed practitioner as defined in 641—Chapter 38 definitions;
- k. Submit a written report of any misdemeanor or felony, any disciplinary action brought against the individual in connection with a certificate or license issued from a certifying or licensing entity, or any disciplinary action brought against the individual by an employer or patient.

42.7(5) Continuing education requirements.

- a. Each individual certified under 641—42.7(136C) shall, during a two-year period, obtain 2 clock hours of continuing education.
- b. Hours may be satisfied by attending courses in podiatric radiography approved by this agency or given by the American Podiatric Medical Association (APMA) or the Iowa Podiatric Medical Society (IPMS).
- c. Proofs of completion shall be retained by the podiatric assistant for four years.
- d. Late submission of continuing education, see 42.2(3)"g."

42.7(6) Recertification.

a. If an individual allows the certification to expire for any reason or if any individual voluntarily terminates certification, the following will apply:

(1) Any individual who wishes to regain certification and makes application within six months of the termination date will be allowed to do so with no additional training or testing required but must complete any delinquent continuing education.

(2) Any individual who wishes to regain certification after two years must complete an approved training program and pass the required examination as required in 42.7(1) and (2).

42.7(7) Any licensed podiatrist who permits an individual to perform podiatric radiography contrary to this chapter shall be subject to discipline by the board of podiatric examiners pursuant to 645—224(272C).

ITEM 36. Amend subrule **45.1(10)**, paragraph "c," subparagraph (2), as follows:

(2) Has one year of documented experience as an industrial radiographer and possesses a current I.D. card issued at least one year prior to the application for a trainer card, and

ITEM 37. Amend subrule **46.5(1)**, paragraph "c," as follows:

c. A tanning facility shall ~~provide~~ require each consumer ~~with a written warning statement to read the information in Appendices 1, 2, and 3 prior to the consumer's initial exposure and annually thereafter, which includes at least the following information:~~

~~(1) The representative list of potential photosensitizing drugs and agents shown in Appendix 1.~~

~~(2) Information regarding potential negative health effects related to ultraviolet exposure, as shown in Appendix 3.~~

~~(3) Basic information on how different skin types respond to tanning (see Appendix 2).~~

~~(4) An explanation of the need to use eyewear.~~

~~(5) (1) The operator shall then request that require the consumer to sign a statement that the information has been read and understood.~~

~~(6) (2) The items in 46.5(1)“e”(1), (2), and (3) information in Appendices 1, 2, and 3 shall be posted in each tanning room.~~

ITEM 38. Amend **641—Chapter 46, Appendix 3**, as follows:

Appendix 3

POTENTIAL NEGATIVE HEALTH EFFECTS

RELATED TO ULTRAVIOLET EXPOSURE

1. Increased risk of skin cancer later in life.
2. Increased risk of skin thickening, age spots, irregular pigmentation, and premature aging.
3. Possibility of burning or rash, especially if using any of the potential photosensitizing drugs and agents. The consumer should consult a physician before using a tanning device if using medications, if there is a history of skin problems or if the consumer is especially sensitive to sunlight.
4. Increased risk of eye damage unless proper eyewear is worn. Iowa law requires the use of proper eyewear during tanning sessions.
  - A. Low pressure tanning systems use a higher percentage of UVB rays which penetrate only the upper layer of skin and can cause burning easier than high pressure tanning systems. Low pressure systems require more frequent sessions to maintain a tan.

High intensity tanning systems use more lamps and shorter tanning sessions than low intensity tanning systems. These are still classified as low pressure systems.

B. High pressure tanning systems use a higher percentage of UVA rays which penetrate deeper and can permanently damage the lower layers of skin and increase the incidences of skin cancers. High pressure systems require fewer and less frequent sessions to maintain a tan.

C. The exposure schedule for each specific unit is shown on the labeling on the tanning unit. Iowa law requires the operator to limit the exposure of each consumer to the exposure schedule shown on the unit in which the consumer is tanning.