

PUBLIC 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 40, “Standards for Protection Against Radiation,” Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials,” Chapter 42, “Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists,” Chapter 44, “Minimum Requirements for Radon Mitigation,” and Chapter 46, “Minimum Requirements for Tanning Facilities,” Iowa Administrative Code.

The following paragraphs itemize the adopted changes:

Items 1, 5, 10, and 56 amend the rules to reflect current federal regulations.

Item 2 amends definitions to meet the Conference on Radiation Control Program Directors (CRCPD) suggested state regulations.

Item 3 increases fees to cover the cost of operating the programs. Examination fees are increased because the examination provider increased the provider’s fee.

Item 4 removes language that is covered elsewhere in rules governing settlements.

Item 6 amends language to indicate an approved registry rather than individual isotopes.

Items 7, 8, and 9 add language involving nationally tracked sources. Items 7, 8, and 9 meet Nuclear Regulatory Commission (NRC) compatibility requirements.

Item 11 is amended to allow radiologic assistants permitted in Chapter 42 to perform fluoroscopic procedures.

Item 12 adopts new language to add additional protection for individuals required to be in the room during certain fluoroscopic procedures.

Items 13 and 14 add language to allow use of hand-held dental X-ray systems.

Item 15 corrects language that was corrected in previous rule makings that removed the term “quality management program.”

Items 16, 17, and 18 correct references.

Items 19 to 40 amend and adopt language to update requirements for fluoroscopic systems in order to meet CRCPD suggested state regulations.

Item 41 adds language for clarification.

Item 42 clarifies the application process for operator certification.

Item 43 corrects a reference.

Items 44, 45, 46, and 47 amend and adopt new requirements for operator continuing education.

Item 48 rescinds language that is incorporated in Item 42 for clarity.

Item 49 amends the time frame for operator certification examinations.

Items 50, 53, and 54 clarify language for operator training programs.

Item 52 rescinds language that is incorporated in Item 51 for clarity.

Item 55 corrects references to radon standards.

Items 51 and 60 allow options for verification of eyewear and cleansing of tanning units.

Item 58 removes the “30 seconds” response requirement and replaces it with “reasonable amount of time” to allow the operators of tanning facilities a greater variety of responses.

Item 59 clarifies what injuries should be reported to the Bureau.

Item 61 adopts new requirements for electronically controlled tanning facilities.

Item 62 removes unnecessary language.

Notice of Intended Action regarding these amendments was published in the Iowa Administrative Bulletin on January 31, 2007, as **ARC 5682B**. A public hearing was held on March 22, 2007. Three individuals attended the hearing and presented two sets of verbal comments. Fifty-five 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 11, the proposed words, "or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152," were not adopted and will be further reviewed based on comments from the regulated community.

2. In Item 12, the sentences, "Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22." were added to allow individuals who are only in the room a short period of time to be exempt from the requirement to wear a protective apron as long as good protection measures were followed. This was a recommendation from the regulated community.

3. In Item 44, in the new adopted subparagraph (6), the words, "hands-on" were removed. Hands-on practice is not allowed for continuing education credit, and this wording was misleading.

4. Language adding a continuing education requirement for a new operator category (Item 44 in the Noticed rules) was not adopted and will be further reviewed based on the comments from the regulated community.

5. Language to clarify who can operate CT, PET/CT, or SPECT/CT equipment (Item 50 in the Noticed rules) was not adopted and will be further reviewed based on the comments from the regulated community.

6. Language adopting new requirements for CT technologists (Item 52 in the Noticed rules) was not adopted and will be further reviewed based on the comments from the regulated community.

The State Board of Health adopted these amendments on March 14, 2007.

These amendments will become effective May 16, 2007.

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

The following amendments are adopted.

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

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 3, 2006~~ April 30, 2007.

ITEM 2. Amend rule ~~641—38.2(136C)~~, definitions of “prescribed dose,” “primary dose monitoring system,” “protective barrier,” “radiation detector,” and “target-to-skin distance (TSD),” as follows:

“Prescribed dose” means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, particle accelerators and X-ray therapy systems, the total dose and dose per fraction as documented in the written directive;

3. For manual brachytherapy, either the total source strength and exposure time or the total ~~doses~~ dose, as documented in the written directive; or

4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Primary dose monitoring system” means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been ~~acquired~~ delivered.

“Protective barrier” means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. “Primary protective barrier” means the material, excluding filters, placed in the useful beam, ~~for protection purposes, to reduce the radiation exposure.~~

2. “Secondary protective barrier” means a barrier sufficient to attenuate the stray radiation to the required degree.

“Radiation detector” means a device which, in the presence of radiation, by either direct or indirect means, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

“Target-to-skin distance (TSD)” means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron virtual source scattering foil to the surface of the irradiated object or patient.

ITEM 3. Amend subrule **38.8(6)** as follows:

Amend paragraph “**a**” as follows:

a. Annual fee. Each individual must submit a \$45 60 initial fee for the first year and \$35 50 annually. These fees are nonrefundable.

Amend paragraph “b” as follows:

b. Examination fee.

~~(1) Each individual making application to take an examination given by the agency as a limited or general nuclear medicine technologist, limited or general radiation therapist, or limited or general diagnostic radiographer, or general radiation therapist as defined in 641—Chapter 42, must pay a nonrefundable fee of \$80 110 each time the individual takes the examination required by 641—Chapter 42.~~

~~(2) Each individual making application to take an examination given by the agency as a limited diagnostic radiographer, limited nuclear medicine technologist, or limited radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of \$85 each time the individual takes the examination required by 641—Chapter 42.~~

~~(3) Each individual making application to take an examination given by the agency as a general nuclear medicine technologist as defined in 641—Chapter 42 must pay a nonrefundable fee of either \$80 or \$160, depending upon the testing organization chosen.~~

ITEM 4. Amend subrule 38.9(4) as follows:

38.9(4) Settlement and compromise. At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. ~~The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge, according due weight to the position of the staff. The presiding officer,~~

~~or if none has been designated, the chief administrative law judge, may order such adjudication of the issues as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.~~

ITEM 5. 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 3, 2006~~ April 30, 2007.

ITEM 6. Amend subrule **39.4(22)**, paragraph “**d**,” subparagraph **(3)**, numbered paragraph “**13**,” first bulleted paragraph, as follows:

- Shall register devices ~~containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, .01 mCi (.37 MBq) of radium-226, or 1 mCi (37 MBq) of any other transuranic (i.e., element with atomic number greater than uranium (92)), or 1000 times the activity indicated in Appendix B of 641—Chapter 39 (excluding hydrogen-3), based on the activity indicated on the label as approved in the Sealed Source Device Registry.~~ Each address for a location of use, as described in 39.4(22)“d”(3)“13,” represents a separate general licensee and requires a separate registration and fee;

ITEM 7. Amend subrule **40.2(2)** by adopting the following new definition in alphabetical order:

“National tracked source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of this chapter. In this context a “sealed source” is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean

material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

ITEM 8. Adopt the following **new** rule 641—40.99(136C):

641—40.99(136C) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subrules 40.99(1) to 40.99(5) for each type of transaction.

40.99(1) Each licensee that manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a. The name, address, and license number of the reporting licensee;
- b. The name of the individual preparing the report;
- c. The manufacturer, model, and serial number of the source;
- d. The radioactive material in the source;
- e. The initial source strength in becquerels (curies) at the time of manufacture; and
- f. The manufacture date of the source.

40.99(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a. The name, address, and license number of the reporting licensee;

- b. The name of the individual preparing the report;
- c. The name and license number of the recipient facility and the shipping address;
- d. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e. The radioactive material in the source;
- f. The initial or current source strength in becquerels (curies);
- g. The date for which the source strength is reported;
- h. The shipping date;
- i. The estimated arrival date; and
- j. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- a. The name, address, and license number of the reporting licensee;
- b. The name of the individual preparing the report;
- c. The name, address, and license number of the person that provided the source;
- d. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- e. The radioactive material in the source;
- f. The initial or current source strength in becquerels (curies);
- g. The date for which the source strength is reported;

h. The date of receipt; and

i. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

40.99(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

a. The name, address, and license number of the reporting licensee;

b. The name of the individual preparing the report;

c. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

d. The radioactive material in the source;

e. The initial or current source strength in becquerels (curies);

f. The date for which the source strength is reported; and

g. The disassemble date of the source.

40.99(5) Each licensee that disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

a. The name, address, and license number of the reporting licensee;

b. The name of the individual preparing the report;

c. The waste manifest number;

d. The container identification with the nationally tracked source;

e. The date of disposal; and

f. The method of disposal.

40.99(6) Reports discussed in subrules 40.99(1) to 40.99(5) must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

- a. The on-line National Source Tracking System;
- b. Electronically using a computer-readable format;
- c. By facsimile;
- d. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or
- e. By telephone with follow-up by facsimile or mail.

40.99(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subrules 40.99(1) to 40.99(5). By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

40.99(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking

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

- a. The name, address, and license number of the reporting licensee;
- b. The name of the individual preparing the report;
- c. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
- d. The radioactive material in the sealed source;
- e. The initial or current source strength in becquerels (curies); and
- f. The date for which the source strength is reported.

ITEM 9. Amend **641—Chapter 40** by adopting **new** Appendix H as follows:

APPENDIX H

NATIONALLY TRACKED SOURCE THRESHOLDS

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

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16.0
Americium-24/Be	60	1,600	0.6	16.0

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

ITEM 10. 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 3, 2006~~ April 30, 2007.

ITEM 11. Amend subrule **41.1(5)**, paragraph “**1**,” subparagraph (2), as follows:

(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. The use of fluoroscopic X-ray systems by radiologic assistants shall be as defined in 641—42.6(136C).

ITEM 12. Amend subrule **41.1(5)** by adopting **new** paragraph “**m**” as follows:

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22.

ITEM 13. Amend subrule **41.1(7)**, paragraph “**c**,” subparagraph **(5)**, by adopting **new** numbered paragraph “**3**” as follows:

3. Portable or hand-held dental X-ray systems designed with a backscatter shield may be used without the additional protective barrier, but the operator must wear a protective apron. The operator must stand directly behind the unit to allow the shield to function as designed.

ITEM 14. Amend subrule **41.1(7)** by adopting **new** paragraph “**i**” as follows:

i. Portable or hand-held dental X-ray systems designed with a backscatter shield shall:

- (1) Be used only where it is impractical to use a portable dental system;
- (2) Be used as the manufacturer indicates;
- (3) Not be used with the backscatter shield removed, if applicable; and
- (4) Be exempted from 41.1(4)“g.”

ITEM 15. Amend subrule **41.2(11)**, paragraph “**c**,” subparagraph **(1)**, as follows:

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee’s written ~~quality management program~~ procedures for maintaining written directives, as appropriate to that individual’s use of radioactive material;

ITEM 16. Amend subrule 41.2(65), 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 17. Amend subrule 41.2(67), introductory paragraph, as follows:

41.2(67) Training for uptake, dilution, and excretion studies. Except as provided in 41.2(75) and 41.2(76), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

ITEM 18. Amend subrule 41.2(68), introductory paragraph, as follows:

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

ITEM 19. Amend subrule **41.3(2)**, definitions of “moving beam radiation therapy” and “nominal treatment distance,” as follows:

“Moving beam radiation therapy” means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

“Nominal treatment distance” means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window₅ of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

ITEM 20. Amend subrule **41.3(5)** by adopting **new** paragraph “g” as follows:

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician’s training has been reviewed and approved by the registrant.

ITEM 21. Amend subrule 41.3(8) as follows:

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

ITEM 22. Amend subrule 41.3(10) as follows:

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and

b. The visiting authorized user meets the requirements of 41.3(5); and

~~b~~ c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

ITEM 23. Amend subrule 41.3(11), introductory paragraph, as follows:

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

ITEM 24. Amend subrule **41.3(16)**, paragraph "**a**," subparagraph **(2)**, as follows:

(2) In addition to the requirements of 41.3(16)"a"(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;

2. After ~~installing or relocating~~ making any change in the location of the therapeutic radiation machine within the treatment room;

3. After relocating the therapeutic radiation machine; or

~~3~~ 4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

ITEM 25. Amend subrule **41.3(17)**, paragraph “**d**,” subparagraph **(9)**, numbered paragraph “**2**,” as follows:

2. ~~Proper operation of the~~ The “BEAM–ON” and termination switches;

ITEM 26. Amend subrule **41.3(17)**, paragraph “**e**,” by adopting **new** subparagraph **(6)** as follows:

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17)“c” and “d” have been met.

ITEM 27. Amend subrule **41.3(18)**, paragraph “**a**,” subparagraph **(2)**, numbered paragraph “**2**,” first bulleted paragraph, as follows:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

ITEM 28. Amend subrule **41.3(18)**, paragraph “**a**,” subparagraph **(4)**, numbered paragraph “**2**,” as follows:

2. If the absorbed dose rate information required by 41.3(18)“a”(9) relates exclusively to operation with a field–flattening filter or beam–scattering foil in place, such filter or foil shall be removable only by the use of tools;

ITEM 29. Amend subrule **41.3(18)**, paragraph “**a**,” subparagraph **(4)**, numbered paragraph “**3**,” third bulleted paragraph, as follows:

- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field–flattening filter(s), and interchangeable beam–scattering foil(s) in use; and

ITEM 30. Amend subrule **41.3(18)**, paragraph “**a**,” subparagraph **(7)**, numbered paragraph “**1**,” as follows:

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

ITEM 31. Amend subrule **41.3(18)**, paragraph “a,” subparagraph (8), by adopting **new** numbered paragraph “4” as follows:

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

ITEM 32. Amend subrule **41.3(18)**, paragraph “a,” subparagraph (15), by adopting **new** numbered paragraph “4” as follows:

4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

ITEM 33. Amend subrule **41.3(18)**, paragraph “a,” subparagraph (16), numbered paragraph “1,” as follows:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or ~~rotational~~ are moving beam radiation therapy has been made at the treatment control panel;

ITEM 34. Amend subrule **41.3(18)**, paragraph “a,” subparagraph (16), numbered paragraph “5,” first and third bulleted paragraphs, as follows:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;

- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

ITEM 35. Amend subrule **41.3(18)**, paragraph “e,” as follows:

e. ~~Full~~ Acceptance testing, commissioning, and full calibration measurements.

(1) ~~Full~~ Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. ~~Before~~ Acceptance testing and commissioning shall be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45 and the manufacturer’s contractual specifications and conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and be performed in accordance with “AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47,” prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. ~~Before medical use under the following conditions~~ The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

• Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, ~~full calibration~~ measurements shall be performed on the ~~effected~~ affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)“e”(1)“3.”

(2) The registrant shall use the dosimetry system described in 41.3(16)“c” to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer’s name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

ITEM 36. Amend subrule **41.3(18)**, paragraph “**f**,” subparagraph (5), numbered paragraphs “2” and “3,” as follows:

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within ~~seven working~~ three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check ~~within 20 working days of completion~~ at intervals not to exceed one month.

ITEM 37. Amend subrule **41.3(18)**, paragraph “**f**,” subparagraph (7), by adopting **new** numbered paragraph “**7**” as follows:

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

ITEM 38. Rescind and reserve subrule **41.3(18)**, paragraph “**f**,” subparagraph (8).

ITEM 39. Amend rule 641—41.3(136C) by adopting **new** subrule 41.3(20) as follows:

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 645—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full-scale; and

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

ITEM 40. Amend **641—Chapter 41, Appendix E, Part V**, by adopting new paragraph **“D”** as follows:

D. NCRP Report 144, “Radiation Protection for Particle Accelerator Facilities” (2003).

ITEM 41. Amend subrule **42.1(2)**, definition of “continuing education course,” as follows:

“Continuing education course” means a planned program of continuing education having sufficient scope and depth of a given subject area directly related to the field of diagnostic radiography, nuclear medicine, or radiation therapy to form an educational unit that is planned, coordinated, administered, and evaluated in terms of educational ~~objects~~ objectives and provides

a defined level of knowledge or specific performance skill. This concept involves the organized presentation of a body of knowledge so that the subject matter is comprehensively covered in sufficient detail to meet the educational objectives of the course.

ITEM 42. Amend subrule 42.2(1) as follows:

42.2(1) ~~Minimum eligibility requirements.~~ Application process. Any individual seeking certification under 641—Chapter 42 shall:

a. Meet minimum eligibility requirements:

~~a.~~ (1) Graduation from high school or its equivalent.

~~b.~~ (2) Attainment of 18 years of age.

~~e.~~ (3) Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients or operators.

b. Satisfactorily complete an agency–approved training program.

c. Satisfactorily complete an agency–approved examination.

d. Upon completion of “b” and “c,” apply to the agency for a permit to practice and pay the fees as specified in 641—subrule 38.8(6).

e. Submit an annual renewal application which includes the fees specified in 641—subrule 38.8(6).

f. Report continuing education as required in 42.2(3).

g. Post the permit at the individual’s place of employment.

h. Work only under the supervision of a licensed practitioner as defined in 641—38.2(136C).

i. 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.

ITEM 43. Amend subrule **42.2(2)**, paragraph “**j**,” as follows:

j. Violating any of the rules of 641—Chapters 38 to 41 42.

ITEM 44. Amend subrule **42.2(3)**, paragraph “**b**,” as follows:

Amend subparagraphs **(2)**, **(3)**, and **(5)** as follows:

(2) Following its review, the agency ~~may~~ will, in consultation with or under predetermined guidance of the technical advisory committee, approve, disapprove, or request additional information on the proposed course.

(3) The agency may, ~~from time to time~~, audit ~~the~~ any continuing education course to verify the adequacy of program content and delivery.

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

Adopt new subparagraphs **(6)** and **(7)** as follows:

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

(7) Courses will be approved for a three-year period and may be given anytime within the three-year period.

ITEM 45. Amend subrule **42.2(3)**, paragraph “**c**,” by adopting new subparagraphs **(4)**, **(5)**, and **(6)**:

(4) Who complete 12.0 hours of tumor boards each two-year reporting period. Tumor board credit is limited to general radiographers, nuclear medicine technologists, and radiation therapists.

(5) Who complete all credit hours in self-studies. A self-study may not be repeated in subsequent reporting periods.

(6) Who pass an advanced ARRT certification examination in a permit-related area. Twenty-four hours will be granted.

ITEM 46. Amend subrule **42.2(3)**, paragraph “g,” subparagraphs (2) and (3), as follows:

(2) Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours plus 3.0 additional penalty hours for limited technologists and 6.0 additional hours for general technologists and the fee required in 641—paragraph 38.8(6)“c” shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and additional penalty hours and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

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

ITEM 47. Amend subrule **42.2(4)**, paragraph “a,” subparagraphs (1) and (3), as follows:

(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.

(3) Any individual who has not renewed certification for at least ~~five~~ two years and wants to regain certification, or who has not applied for certification within ~~five~~ two years of the completion date of the original training course, will need to complete a recertification program approved by the department of not less than 24 contact hours for general certifications and 12 contact hours for limited certifications which specifically applies to the area of certification.

ITEM 48. Rescind and reserve subrule **42.2(5)**.

ITEM 49. Amend subrule 42.2(8) as follows:

42.2(8) Examinations. All individuals seeking certification under 641—Chapter 42 must pass a written examination ~~within six months of the date of the initial certification. The temporary six-month permit will be issued to allow the~~ before the permit can be issued. The individual is allowed to practice under the direct supervision of a licensed practitioner, an authorized user listed on a radioactive materials license, or a permitted individual with the permit in the same or higher category until the permit is issued provided the test is pending. The individual will be issued an annual permit upon passing the examination. Individuals who fail the examination three times will be required to satisfactorily complete the training course again.

ITEM 50. Amend subrule **42.2(7)** as follows:

a. General diagnostic radiographer. Successful completion of a Joint Review Committee on Education in Radiologic Technology approved course of study, certification by the American Registry of Radiologic Technologists or the American Registry of Clinical Radiography

Technologists, or equivalent agency–approved training courses to prepare the student to demonstrate competency in the following areas:

ITEM 51. Rescind subrule **42.3(1)**, paragraph “**d**,” and adopt the following new paragraph “**d**” in lieu thereof:

d. Graduates of programs recognized by the Iowa department of public health in consultation with the professional societies and boards of examiners for appropriate courses of study in diagnostic radiography will be considered to meet the requirements of this rule.

ITEM 52. Rescind and reserve subrule **42.3(2)**.

ITEM 53. Amend subrule **42.4(2)**, paragraph “**a**,” introductory paragraph, as follows:

a. General nuclear medicine technologist. Successful completion of a Joint Review Committee on Educational Programs in Nuclear Medicine approved course of study or equivalent agency–approved training courses designed to prepare the student to demonstrate competency in the following:

ITEM 54. Amend subrule **42.5(2)**, paragraph “**a**,” introductory paragraph, as follows:

a. General radiation therapist. Successful completion of a Joint Committee on Education in Radiologic Technology approved course of study or equivalent agency–approved training courses designed to prepare the student to demonstrate didactic and clinical competency in radiation therapy including, but not limited to, anatomy, physiology, radiation physics, radiation protection and exposure, quality assurance, radiation oncology treatment techniques, dosimetry, radiation oncology and pathology, radiology, oncologic patient care and management.

ITEM 55. Amend subrule **44.3(4)**, paragraph “**c**,” as follows:

c. The credentialed person shall comply with department standards and all the requirements as stated in EPA’s Radon Mitigation Standards (RMS) EPA 402–R–93–078,

October 1993 (Revised April 1994) and ASTM E2121. ~~(NOTE: EPA has incorporated E2121 by reference and retained EPA's Radon Mitigation Standards (RMS) in effect until at least 2007), and must comply with EPA's Radon Mitigation Standards (RMS) EPA 402 R 93 078, October 1993 (Revised April 1994) and ASTM E2121, which states that all~~ All “shoulds” in the above document are shall be “shalls” according to department standards.

ITEM 56. Amend rule ~~641—46.1(136D)~~, first unnumbered paragraph, as follows:

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 5, 2004~~ April 3, 2007.

ITEM 57. Amend subrule ~~46.5(8)~~, paragraph “d,” as follows:

d. A tanning facility operator shall not allow a consumer to use a tanning device if that consumer does not use the protective eyewear required by this subrule. To verify that a consumer has the proper eyewear, the operator must:

(1) Ask to see the eyewear before the consumer enters the tanning room; or

(2) Provide disposable eyewear in the tanning room at all times.

ITEM 58. Amend subrule ~~46.5(9)~~, paragraph “a,” subparagraph (2), as follows:

(2) The operator or emergency help can reach the consumer within ~~30 seconds~~ a reasonable amount of time after being summoned.

ITEM 59. Amend subrule ~~46.5(9)~~, paragraph “d,” introductory paragraph, as follows:

d. Any tanning injury not requiring a physician's care and any resulting changes in tanning sessions shall be noted in the consumer's file. A written report of any tanning injury requiring a physician's care shall be forwarded by the permit holder to the department within five working days of its occurrence or knowledge thereof. The report shall include:

ITEM 60. Amend subrule ~~46.5(9)~~, paragraph “g,” as follows:

g. Contact surfaces of tanning devices shall be:

~~(1) cleansed~~ Cleansed by the operator with a cleansing agent between each use; ~~or~~

~~(2) the contact surfaces may be covered~~ Covered by a nonreusable protective material during each use; or

(3) Cleansed by the consumer provided the following conditions are met:

1. The operator instructs the consumer annually on how to properly cleanse the unit;

2. The consumer annually signs a statement stating that the consumer agrees to cleanse the unit after each use;

3. Signs are posted in each tanning room reminding the consumer to cleanse the tanning unit after each use and stating the proper way to cleanse the unit; and

4. The operator cleanses the tanning unit at least once a day.

ITEM 61. Amend rule 641—46.5(136D) by adopting **new** subrule 46.5(12) as follows:

46.5(12) Requirements for electronically controlled facilities. Electronically controlled facilities are those facilities that rely on electronic means to monitor consumers.

a. Entry into the facility is allowed by card only. Two individuals may not enter under the same card. The card is specifically activated for tanning use if the facility offers other activities.

b. Police and all emergency services will have access to the facility through a key box located outside the entrance of the facility.

c. The tanning unit will not activate if the card is not programmed for tanning. The card will not activate if two individuals are in the tanning room.

d. The consumer must sign a tanning agreement that states the number of minutes per session, that the consumer agrees to wear protective eyewear, that the consumer will cleanse the unit after tanning, and that the consumer is aware of the emergency access in each room.

e. The card will be programmed for the number of minutes the consumer is allowed to tan. The card may be reprogrammed for an increase in minutes per session only after the consumer has reviewed and re-signed the Tanning Agreement. After 30 consecutive days without the consumer's accessing the tanning facility, the card will be deactivated and the consumer must reapply to access the tanning unit.

f. The operator will demonstrate to each consumer how to properly cleanse the unit after tanning, including the top, bottom, and handles. A sign will be placed in each room explaining the cleansing process. The operator will cleanse the units at least once a day when they are in use.

g. Free disposable eyewear will be placed in each room along with a sign stating that the disposable eyewear is available and that eyewear must be worn.

h. An emergency call button or device will be placed in each tanning room conveniently located within reach of the tanning bed. This device will call the operator or emergency personnel.

i. During annual inspections, the inspector may ask any consumer about any of the above processes.

ITEM 62. Amend **641—Chapter 46, Appendix 2**, as follows:

Appendix 2

SUN-REACTIVE SKIN TYPES USED IN CLINICAL PRACTICE

SKIN	SKIN REACTIONS TO SOLAR	EXAMPLES
------	-------------------------	----------

TYPE	RADIATION ^(a) EXAMPLES	
I	Always burns easily and severely (painful burn). Tans little or none and peels.	People most often with fair skin, blue eyes, freckles. Unexposed skin is white.
II	Usually burns easily and severely (painful burn). Tans minimally or lightly, also peels.	People most often with fair skin; red or blonde hair; blue, hazel or even brown eyes. Unexposed skin is white.
III	Burns moderately and tans about average.	Normal average Caucasoid. Unexposed skin is white.
IV	Burns minimally, tans easily, and above average with each exposure. Exhibits IPD (immediate pigment darkening) reaction.	People with white or light brown skin, dark skin, dark brown hair, dark eyes. Unexposed skin is brown.
V	Rarely burns, tans easily and substantially. Always exhibits IPD reaction.	Brown-skinned person. Unexposed skin is brown.
VI	Never burns and tans profusely; exhibits IPD reaction.	Unexposed skin is black.

(a) Based in the first 45–60 minutes (= 2–3 minimum erythema dose) exposure of the summer sun (early June) at sea level.

(b) Rescinded IAB 3/29/06, effective 5/3/06.