ARC 8982B

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," and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," Iowa Administrative Code.

Items 1, 9, 21, 32, and 62 amend rules to reflect current federal regulations. Items 5 and 6 add electronic brachytherapy devices to subrule 38.8(1). Item 7 adds the radioactive material fee schedule to rule 641—38.8(136C) and includes a general license registration fee. Item 8 clarifies payment requirements to obtain permits for radioactive material shipments. Item 10 resolves comment #1 in Nuclear Regulatory Commission (NRC) letter to the Department dated 9/16/2009. Item 31 corrects the location of values for Sulfer-35. Item 33 clarifies the requirement for assay of doses. Item 63 ensures proper training is completed prior to the examination. The remaining items amend the rules to meet NRC compatibility requirements.

Notice of Intended Action was published in the May 19, 2010, Iowa Administrative Bulletin as **ARC 8762B**. Comments were received from one individual. Most of the changes suggested cannot be made because the changes would not be compatible with federal requirements. However, subparagraph 41.2(34)"b"(2) in Item 36 has been changed as a result of the comments. Subparagraph 41.2(34)"b"(2) now reads as follows:

"(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day."

In addition, several nonsubstantive, technical changes have been made.

These amendments were adopted by the State Board of Health on July 14, 2010.

These amendments will become effective on September 15, 2010.

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

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

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 9, 2008~~ September 15, 2010.

ITEM 2. Rescind the definition of "Authorized medical physicist" in rule **641—38.2(136C)**.

ITEM 3. Amend rule **641—38.2(136C)**, definitions of "By-product material," "Total effective dose equivalent" and "Waste," as follows:

"By-product material" means:

1. ~~(1) any~~ Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material~~, and~~;

2. ~~(2) the~~ The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "by-product material" within this definition~~.~~;

3. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity or any material that:

- Has been made radioactive by use of a particle accelerator; and

● Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

● The Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat to the public health and safety or the common defense and security similar to the threat posed by a discrete source of radium-226; and

● Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"Total effective dose equivalent" (TEDE) means the sum of the ~~deep~~ effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

"Waste" means those low-level radioactive wastes containing source, special nuclear, or by-product material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste ~~has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (1)~~ means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material as defined in ~~Section 11e(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (2) classified as low-level radioactive waste consistent with existing law and in accordance with (1) by the U.S. Nuclear Regulatory Commission~~ paragraphs "2," "3" and "4" of the definition of "by-product material" set forth in this chapter.

ITEM 4. Adopt the following **new** definitions of "Consortium," "Discrete source" and "Positron emission tomography (PET) radionuclide production facility" in rule **641—38.2(136C)**:

"Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a federal facility or a medical facility.

"Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

"Positron emission tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

ITEM 5. Amend paragraph **38.8(1)"a"** as follows:

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

ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	$51	$1500
2. Osteopathy	$51	$1500
3. Chiropractic	$51	$1500
4. Dentistry	$39	$1000
5. Podiatry	$39	$1000
6. Veterinary Medicine	$25	–

Type of X-ray machine	Fee per tube	Maximum fee
7. (Industrial/Nonmedical Use)	$50	–
8. Food Sterilization	$1000	–
9. Accelerators and Electronic Brachytherapy Units	$100	–
10. Electron Microscope	$20	–
11. Bone Densitometry	$25	–

Fees for radiation machines not listed in the above schedule shall not be less than $50 per unit/tube.

ITEM 6. Amend subparagraph **38.8(1)"b"(3)** as follows:

(3) Industrial and oncology accelerator registrants and electronic brachytherapy registrants shall pay for each inspection a fee of $400 for the first unit and $100 for each additional unit.

ITEM 7. Rescind subrule 38.8(2) and adopt the following **new** subrule in lieu thereof:

38.8(2) *Radioactive material fee schedule.* Fees associated with the possession and use of radioactive materials in Iowa shall not exceed those specified in 10 CFR 170.31 and 10 CFR 171.16. The following fee schedule shall apply.

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(3.L.)	01100	AAB	Academic Type A Broad	$5,000	1	$10,500
(8.A.)	03710	CD	Civil Defense	$1,000	5	$1,000
(3.E.)	03510	I1	Irradiators, Self-Shielding <10,000 Curies	$2,000	5	$650
(3.O.)	03320	IR1	Industrial Radiography – Temporary Job Sites	$4,500	1	$4,300
(3.P.)	03120	FG	Measuring Systems – Fixed Gauge	$1,300	5	$650
(3.P.)	03121	PG	Measuring Systems – Portable Gauge	$1,300	5	$650
(3.P.)	02410	IVL	*In-Vitro* Testing Laboratory	$1,300	5	$650
(7.C.)	02230	HDR	High Dose Rate Afterloader	$2,300	1	$3,400
(7.C.)	02120	M1	Medical – Diagnostic & Therapy	$2,300	3	$1,500
(7.C.)	02121	M2	Medical – Diagnostic Only	$2,300	4	$1,200
(7.C.)	02240	MET	Medical – Diagnostic, Therapeutic, Emerging Technologies	$2,300	2	$2,000
(3.S.)	03210	PET	Accelerator-Produced RAM	$3,000	1	$4,300
(3.C.)	02500	NP	Nuclear Pharmacy	$3,000	1	$3,500
(7.C.)	02231	NV1	Nuclear Medical Van	$2,300	2	$1,800
(7.C.)	22160	PMM	Pacemaker – By-Product and/or SNM	$2,300	T	Note 5
(3.M.)	03620	RD2	Research & Development – Other	$2,500	3	$1,350

	Program Code	Category	Type	New License Fee	Inspection Priority	Annual Fee
(2.C.)	11300	SM1	Source Material, Other, >150 Kilograms	$6,000	3	$2,250
(1.D.)	22120	SNM2	SNM Plutonium – Neutron Source	$1,500	5	$500
(3.P.)	03221	CAL	Calibration and W/L Tests	$1,300	5	$650
(3.P.)	03122	XRF	X-Ray Fluorescent Analyzer	$1,300	7	$650
(3.P.)	02400	VMT	Veterinary Medicine – Therapy	$1,300	3	$650
(3.B.)	03214	MD	Manufacturing/Distribution	$3,500	3	$1,800

Notes:

1. Reciprocity fee is $1,800 annually (180 days).
2. Inspection priorities are based on NRC inspection manual chapter 2800. Priority "T" is a telephonic contact and is not considered an inspection.
3. License amendment fee for all categories is $400.
4. Annual fees are due no later than September 1 of each year. A 10% late charge will be assessed per month for late payments. Licensees with more than two authorized locations of use will be charged an additional 10% of the annual fee per location.
5. Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses with the agency.
6. General license registration fee is $250 annually on registration anniversary.

ITEM 8. Amend paragraph **38.8(11)"b"** as follows:

b. All fees must be ~~received~~ paid by the ~~department~~ shipper prior to shipment. ~~Fees must be in the form of a check or money order made payable to the Iowa Department of Public Health and sent to the Iowa Bureau of Radiological Health, Lucas State Office Building, 5th Floor, Des Moines, Iowa 50319.~~ Shippers must request an application for a permit to ship radioactive material from the Iowa Department of Transportation, Office of Motor Carrier Services. Assistance may be obtained by calling the Bureau of Radiological Health at (515)281-3478. Other methods of fee payment may be considered by the department on a case-by-case basis upon request of the shipper. A request for an alternative method of payment must be made to the department prior to shipment.

ITEM 9. 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 ~~September 2, 2009~~ September 15, 2010.

ITEM 10. Amend subparagraph **39.4(3)"c"(1)** as follows:

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

- 25 millicuries (925 MBq) of tritium per timepiece;
- 5 millicuries (185 MBq) of tritium per hand;
- 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

- 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;
- 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).~~;~~
- One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

2. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
- For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1 μGy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.
- ~~One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to the effective date of this rule.~~

3. to 7. No change.

Any person who desires to apply by-product material to, or to incorporate by-product material into, the products exempted in subparagraph 39.4(3)*"c"*(1), or who desires to initially transfer for sale or distribution such products containing by-product material, should apply for a specific license with the Nuclear Regulatory Commission pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to subparagraph 39.4(3)*"c"*(1).

ITEM 11. Amend subparagraph **39.4(3)"c"(3)** as follows:

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from the requirements contained in 641—Chapters 38, ~~39,~~ 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section ~~32.27~~ 32.26 of 10 CFR Part 32; or a licensing state pursuant to 39.4(29)*"c,"* which authorizes the initial transfer of the product for use under this rule.

2. to 4. No change.

ITEM 12. Amend subparagraph **39.4(22)"d"(2)** as follows:

(2) The general license in 39.4(22)*"d"*(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license by this agency issued under 39.4(29)*"d"*; or an equivalent specific license issued by the NRC or an agreement state or a licensing state~~,~~; or an equivalent specific license issued by a state with provisions comparable to 39.4(29)*"d,"* which authorizes distribution of the devices. The devices must have been received from one of the specific licensees described in 39.4(22)*"d"*(2) or through a transfer made under 39.4(22)*"d"*(3).

ITEM 13. Adopt the following **new** paragraph **39.4(22)"k"**:

k. Certain items and self-luminous products containing radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with 39.4(22)*"k"*(2), (3), and (4), radium-226 contained in the following products manufactured prior to November 30, 2007.

1. Antiquities originally intended for use by the general public. For the purposes of this subrule, "antiquities" means products originally intended for use by the general public and distributed in the late nineteenth and early twentieth centuries including, but not limited to, radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

2. Intact and non-intact timepieces containing greater than 1 microcurie (0.037 megabecquerel), and timepiece hands and dials no longer installed in timepieces.

3. Luminous items installed in air, marine, or land vehicles.

4. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

5. Small radium sources containing no more than 1 microcurie (0.037 megabecquerel) of radium-226. For the purposes of this subrule, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the agency.

(2) Persons who acquire, receive, possess, use, or transfer by-product material under the general license issued in 39.4(22)*"k"*(1) shall comply with the provisions of 641—40.95(136C) and 641—40.96(136C), but shall be exempt from the other requirements of 641—Chapter 40, to the extent that the receipt, possession, use, or transfer of by-product material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under 39.4(24).

(3) Any person who acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license in 39.4(22)*"k"*(1) shall:

1. Notify the agency if there is any indication of possible damage to the product which could result in a loss of the radioactive material. A report containing a brief description of the event and the remedial action taken must be furnished to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa, within 30 calendar days.

2. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 641—40.77(136C) or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the agency.

3. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

4. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under 39.4(24), or equivalent NRC or agreement state requirements, or as otherwise approved by the agency.

5. Respond in writing to a written request from the agency to provide information relating to the general license within 30 calendar days of the request, or other time specified in the request.

(4) The general license in 39.4(22)*"k"*(1) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

ITEM 14. Adopt the following **new** paragraphs **39.4(24)"g"** and **"h"**:

g. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

(1) Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material as registered with a state under provisions comparable to 10 CFR 32.210; or

(2) Contain the information identified in 10 CFR 32.210(c); or

(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007, that are not registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all the categories of information specified in 10 CFR 32.210(c), the applicant must provide:

1. All available information identified in 10 CFR 32.210(c) concerning the source and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description

of radiation safety features, the intended use and associated operating experience, and the results of a current leak test.

h. An application from a medical facility or an educational institution to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in the facility's or educational institution's consortium authorized for medical use under 641—41.2(136C) or equivalent NRC or agreement state requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this chapter or equivalent NRC or agreement state requirements for a PET production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 39.4(29)*"j"*(1)"2."

(3) Identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 39.4(29)*"j"*(2)"2."

(4) Information identified in 39.4(29)*"j"*(1)"3" on the PET drugs to be noncommercially transferred to members of the facility's consortium.

ITEM 15. Amend paragraph **39.4(29)"f"** as follows:

f. ~~Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 39.4(22)"g."~~ An application for a specific license to manufacture or initially transfer calibration ~~and~~ or reference sources containing americium-241~~, plutonium~~ or radium-226 for distribution to persons generally licensed under 39.4(22)*"g"* will be approved if:

(1) The applicant satisfies the general requirements of 39.4(25); ~~and~~

(2) The applicant ~~satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, or their equivalent.~~ submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

1. Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

2. Details of construction and design;

3. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

4. Procedures for and the results of prototype testing of sources, which are designed to contain more than 0.005 microcuries of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

5. Details of quality control procedures to be followed in the manufacture of the source;

6. Description of labeling to be affixed to the source or storage container for the source;

7. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the safety of the source.

(3) Each source contains no more than 5 microcuries of americium-241 or radium-226.

(4) The agency determines, with respect to any type of source containing more than 0.005 microcuries of americium-241 or radium-226, that:

1. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

2. The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR Part 32.102, Schedule C.

(5) Each person licensed under this subrule affixes to each source, or storage container for the source, a label in accordance with 10 CFR Part 32.58.

(6) Each person licensed under this subrule conducts a leak test on sealed sources in accordance with 10 CFR Part 32.59.

ITEM 16. Amend subparagraph **39.4(29)"h"(2)** as follows:

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

1. to 7. No change.

8. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

ITEM 17. Amend subparagraph **39.4(29)"j"(1)** as follows:

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing by-product material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. No change.

2. The applicant submits evidence that the applicant is at least one of the following:

- Registered ~~or licensed~~ with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the ~~manufacturer~~ manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
- Registered or licensed with a state agency as a drug manufacturer;
- Licensed by the Iowa board of pharmacy ~~examiners~~ as a nuclear pharmacy; ~~or~~
- Operating as a nuclear pharmacy within a federal medical institution; or
- A positron emission tomography (PET) drug production facility registered or licensed with a state agency;

3. and 4. No change.

ITEM 18. Amend subparagraph **39.4(29)"j"(2)** as follows:

(2) A licensee as described by 39.4(29)*"j"*(1)"2":

1. May prepare radioactive drugs for medical use, as defined in 641—38.2(136C), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 39.4(29)*"j"*(2)"2" and 39.4(29)*"j"*(2)"3" or an individual under the supervision of an authorized nuclear pharmacist as specified in 641—paragraph 41.2(11)*"c."*

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),
- This individual meets the requirements specified in 641—subrules 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)*"j"*(2)"~~2~~ 3."

3. May designate a pharmacist (as defined in 641—subrule 41.2(2)) as an authorized nuclear pharmacist if the individual ~~is identified as of July 9, 1997, as an "authorized user" on a nuclear pharmacy license issued by the agency, the Nuclear Regulatory Commission or an Agreement State~~ was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

4. No change.

5. Shall provide to the agency a copy of each individual's:

- Certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in 641—paragraph 41.2(78)*"a"* with the written attestation signed by a preceptor as required by 641—paragraph 41.2(78)*"c"*; or
- NRC or agreement state license; or
- ~~Permit issued by a licensee of broad scope; and~~ NRC master materials licensee permit; or
- Permit issued by a licensee or NRC master materials permittee of broad scope or authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

- Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and
- State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(29)*"j"*(2)"2," first and third bulleted paragraphs, the individual to work as an authorized nuclear pharmacist.

ITEM 19. Amend subrule 39.4(32) as follows:

39.4(32) *Specific terms and conditions of licenses.*

a. to *d.* No change.

e. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 641—subrule 41.2(34). The licensee shall record the results of each test and retain each record for three years after the record is made.

~~*e.*~~ *f.* Each general licensee that is required to register by 39.4(21) or 39.4(22) and each specific licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

~~*f.*~~ The notification specified in 39.4(32)*"e f"* shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

g. (1) Authorization under 39.4(29)*"h"* to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in the licensee's consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(2) Each licensee authorized under 39.4(29)*"h"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the licensee's consortium shall:

1. Satisfy the labeling requirements in 39.4(29)*"j"*(1)"4" for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of the licensee's consortium.

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of the licensee's consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 39.4(29)*"j"*(3).

(3) A licensee that is a pharmacy authorized under 39.4(24)*"h"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy's consortium shall require that any individual who prepares PET radioactive drugs shall be:

1. An authorized nuclear pharmacist who meets the requirements in 39.4(29)*"j"*(2)"2," or

2. An individual under the supervision of an authorized nuclear pharmacist as specified in 641—subrule 41.2(11).

(4) A pharmacy authorized under 39.4(29)*"j"* to produce PET radioactive drugs for noncommercial transfer to medical use licensees in the pharmacy's consortium that allows an individual to work as an authorized nuclear pharmacist shall meet the requirements in 39.4(29)*"j"*(2)"5."

ITEM 20. Adopt the following **new** radioactive material in alphabetical order in **641—Chapter 39**, Appendix G:

Radioactive Material	Release Fraction	Quantity (curies)
Radium-226	.001	100

ITEM 21. 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 ~~July 9, 2008~~ September 15, 2010.

ITEM 22. Rescind subrule 40.15(3) and adopt the following **new** subrule in lieu thereof:

40.15(3) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the agency. The assigned deep dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

ITEM 23. Amend paragraph **40.70(1)"d"** as follows:

d. As authorized pursuant to 641—40.71(136C), 641—40.72(136C), 641—40.73(136C), ~~or~~ 641—40.74(136C), or 641—40.77(136C).

ITEM 24. Adopt the following **new** subrule 40.75(4):

40.75(4) Any licensee shipping licensed material, as defined in paragraphs "3" and "4" of the definition of "by-product material" set forth in 641—Chapter 38, intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

ITEM 25. Adopt the following **new** rule 641—40.77(136C):

641—40.77(136C) Disposal of certain by-product material.

40.77(1) Licensed material, as defined in paragraphs "3" and "4" of the definition of "by-product material" set forth in 641—Chapter 38, may be disposed of in accordance with 10 CFR Part 61, even though the material is not defined as low-level radioactive waste. Therefore, any licensed by-product material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of 641—40.75(136C).

40.77(2) A licensee may dispose of licensed material, as defined in paragraphs "3" and "4" of the definition of "by-product material" set forth in 641—Chapter 38, at a disposal facility authorized to dispose of such material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

ITEM 26. Amend subrule 40.97(3) as follows:

40.97(3) All licensees or registrants who make reports pursuant to ~~40.97(1)~~ 641—40.97(136C) or 641—40.98(136C) to the agency regarding exposure of an identified occupationally exposed individual, or of an identified member of the public, to radiation or radioactive material shall also provide a copy of the report to the individual or member of the public. Transmittal shall be at the same time as the transmittal to the agency.

ITEM 27. Rescind subrule 40.112(2) and adopt the following **new** subrule in lieu thereof:

40.112(2) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of 641—40.86(136C). The licensee or registrant shall provide to each individual monitored under 641—40.37(136C) an annual report of the dose received in that monitoring year if:

a. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue, or

b. The individual requests the individual's annual dose report.

ITEM 28. Amend subrule 40.112(4) as follows:

40.112(4) When a licensee or registrant is required pursuant to 641—40.96(136C), 641—40.97(136C), or 641—40.98(136C) to report to the agency any exposure of an individual to ~~sources of~~ radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the individual's exposure data included ~~therein~~ in the report to the agency. Such reports shall be transmitted at a time not later than the transmittal to the agency.

ITEM 29. Adopt the following **new** entries in alphabetical order in **641—Chapter 40**, Appendix B, List of Elements:

Name	Symbol	Atomic Number
Nitrogen	N	7
Oxygen	O	8

ITEM 30. Adopt the following **new** entries in numerical order in **641—Chapter 40**, Appendix B, Table:

Atomic Radio-nuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 INHALATION ALI (µCi)	Table I Occupational Values Col. 3 INHALATION DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
7 Nitrogen-13[2]	Submersion[1]			4E-6	2E-8	-	-
8 Oxygen-15[2]	Submersion[1]			4E-6	2E-8	-	-

ITEM 31. Amend number **"16,"** Sulfur-35, in **641—Chapter 40**, Appendix B, Table, as follows:

Atomic Radio-nuclide No.	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 INHALATION ALI (µCi)	Table I Occupational Values Col. 3 INHALATION DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
16 Sulfur-35	Vapor	~~1E+4~~	~~6E-6~~ 1E+4	~~2E-8~~ 6E-6	2E-8		

ITEM 32. Amend paragraph **41.2(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~September 2, 2009~~ September 15, 2010.

ITEM 33. Amend subrule 41.2(19) as follows:

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains ~~more than 30 microcuries (1.1 megabecquerels) of~~ a photon-emitting radionuclide;

~~*b.* Assay, before medical use, the activity of each radiopharmaceutical dosage of a photon-emitting radionuclide to verify that the dosage does not exceed 30 microcuries (1.1 MBq);~~

~~*c.*~~ *b.* Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements;

~~*d.*~~ *c.* Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

~~*e.*~~ *d.* Retain a record of the assays required by 41.2(19)*"a"* for three years. To satisfy this requirement, the record shall contain the:

(1) to (5) No change.

ITEM 34. Amend subrule 41.2(31) as follows:

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion ~~and imaging~~ studies any unsealed radioactive material prepared for medical use that ~~is either~~:

a. ~~Obtained~~ Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent ~~U.S. Nuclear Regulatory Commission~~ NRC or agreement state requirements~~;~~ or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. ~~Prepared~~ Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist~~,~~;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs~~; or before May 3, 2006, who meets the requirements of 10 CFR 35.290~~; or

(3) No change.

c. ~~Obtained~~ Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. ~~Prepared~~ Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

ITEM 35. Amend subrule 41.2(33) as follows:

41.2(33) *Use of ~~radiopharmaceuticals, generators, and reagent kits~~ unsealed by-product material for imaging and localization studies for which a written directive is not required.* Except for ~~the~~ quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that ~~is either~~:

a. ~~Obtained~~ Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. ~~Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69), or an individual under the supervision of either as specified in 41.2(11);~~ Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33)*"b"*(1) or the physician who is an authorized user in 41.2(33)*"b"*(2); or

c. ~~Obtained~~ Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. ~~Prepared~~ Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

ITEM 36. Amend subrule 41.2(34) as follows:

41.2(34) *Permissible molybdenum-99 ~~concentration~~, strontium-82, and strontium-85 concentrations.*

a. A licensee shall not administer to humans a radiopharmaceutical ~~containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).~~ that contains:

(1) More than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.02 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee preparing ~~technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.~~:

(1) Technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract; or

(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day.

c. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include~~, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.~~:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

d. A licensee shall report immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in ~~41.2(34)*"a."*~~ 41.2(34)*"a"*(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34)*"a"*(2).

ITEM 37. Amend subrule 41.2(37) as follows:

41.2(37) *Use of ~~radiopharmaceuticals for therapeutic use or~~ unsealed by-product material for which a written directive is required.* ~~Material must be~~ A licensee may use any unsealed by-product material prepared for medical use and for which a written directive is required that:

a. ~~Obtained~~ Is obtained from ~~a manufacturer or preparer licensed by the NRC or an agreement state to manufacture and prepare by-product material for medical use; or~~:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. ~~Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69), or an individual under the supervision of either as specified in 41.2(11); or~~ Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69); or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37)*"b"*(1) or the physician who is an authorized user in 41.2(37)*"b"*(2); or

c. ~~Obtained~~ Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. ~~Prepared~~ Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

ITEM 38. Amend subparagraph **41.2(65)"a"(2)** as follows:

(2) Require all candidates for certification to:

1. No change.

2. Have two years of either full-time practical training or supervised experience in medical physics ~~either~~ under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), ~~or~~ 41.2(69), or 41.2(75); and

3. No change.

ITEM 39. Amend paragraph **41.2(67)"b"** as follows:

b. Is an authorized user under 41.2(68) or 41.2(69)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.190, 35.290, or 35.390, or~~ meets equivalent NRC or agreement state requirements; or

ITEM 40. Amend subparagraph **41.2(67)"c"(1)** as follows:

(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. No change.

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), ~~or~~ 41.2(69)~~,~~ or 41.2(75) or ~~before May 3, 2006, the requirements in 10 CFR 35.190, 35.290, or 35.390, or~~ equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and

ITEM 41. Amend subparagraph **41.2(67)"c"(2)** as follows:

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), ~~or~~ 41.2(69)~~,~~ or 41.2(75) ~~or before May 3, 2006, the requirements in 10 CFR 35.190, 35.290, or 35.390,~~ or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(67)*"a"*(1) or 41.2(67)*"c"*(1) and

has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31).

ITEM 42. 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), the licensee shall require the authorized user of unsealed radioactive material ~~specified in~~ for the uses authorized under 41.2(33) to be a physician who:

ITEM 43. Amend paragraph **41.2(68)"b"** as follows:

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, or ~~before May 3, 2006, meets the requirements in 10 CFR 35.290, or~~ equivalent NRC or agreement state requirements; or

ITEM 44. Amend subparagraph **41.2(68)"c"(1)** as follows:

(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. No change.

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); ~~or~~ 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, and 41.2(69)~~,~~; 41.2(75); or ~~before May 3, 2006, meets the requirements in 10 CFR 35.290, or~~ equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

ITEM 45. Amend subparagraph **41.2(68)"c"(2)** as follows:

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68); ~~or~~ 41.2(69) and 41.2(68)*"c"*(1)"2," seventh bulleted paragraph~~,~~; 41.2(75); or ~~before May 3, 2006, meets the requirements in 10 CFR 35.290, or~~ equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(68)*"a"*(1) or 41.2(68)*"c"*(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

ITEM 46. Amend subparagraph **41.2(69)"b"(1)** as follows:

(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. No change.

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, or~~ equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)~~*"b,"*~~*"b"* ~~or before May 3, 2006, meets the requirements in 10 CFR 35.390(b)~~ must also have

experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Reserved.
- Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

– Oral administration of less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131, for which a written directive is required;

– Oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);

– Parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; or

– Parenteral administration of any other radionuclide for which a written directive is required; and

ITEM 47. Amend subparagraph **41.2(69)"b"(2)** as follows:

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)*"a"*(1) and 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or 41.2(69)*"b"*(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, or~~ equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)*"b"* ~~or before May 3, 2006, meets the requirements in 10 CFR 35.390(b),~~ must have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status.

ITEM 48. Amend paragraph **41.2(69)"c"** as follows:

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) or quantities greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels), see 41.2(81) or 41.2(82).

ITEM 49. Amend subrule 41.2(70), introductory paragraph, as follows:

41.2(70) *Training for use of manual brachytherapy sources.* Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized ~~in~~ under 41.2(43) to be a physician who:

ITEM 50. Amend paragraph **41.2(70)"b"** as follows:

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. No change.

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490, or~~ equivalent NRC or agreement state requirements at a medical institution, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and
- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490, or~~ equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70)*"b"*(1)"2"; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490, or~~ equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70)*"a"*(1) or 41.2(70)*"b"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses ~~in~~ authorized under 41.2(43).

ITEM 51. Amend paragraph **41.2(71)"a"** as follows:

a. Is an authorized user under 41.2(70)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.491, or~~ equivalent NRC or agreement state requirements; or

ITEM 52. Amend subparagraph **41.2(71)"b"(3)** as follows:

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70)~~,~~ ~~or~~ 41.2(71)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.491, or~~ equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71)*"b"*(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

ITEM 53. Amend subrule 41.2(73), introductory paragraph, as follows:

41.2(73) *Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.* Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized ~~in~~ under 41.2(49) to be a physician who:

ITEM 54. Amend paragraph **41.2(73)"b"** as follows:

b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

1. No change.
2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.690, or~~ equivalent NRC or agreement state requirements at a medical institution, involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and

- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73)~~,~~ or 41.2(75) or ~~before May 3, 2006, meets the requirements in 10 CFR 35.690, or~~ equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)*"b"*(1)"2"; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)*"a"*(1) or 41.2(73)*"b"*(1) and (2), and 41.2(73)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73)~~,~~ or 41.2(75) or ~~before May 3, 2006, the requirements in 10 CFR 35.690, or~~ equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

ITEM 55. Amend subparagraph **41.2(74)"a"(2)** as follows:

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. No change.

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), ~~or~~ 41.2(73), or 41.2(75); and

ITEM 56. Amend subparagraph **41.2(74)"b"(2)** as follows:

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74)*"a"*(1) and (2) and 41.2(74)*"c"* or 41.2(74)*"b"*(1) and 41.2(74)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74)~~,~~ or 41.2(75), ~~before May 3, 2006, the requirements in 10 CFR 35.51,~~ or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

ITEM 57. Adopt the following **new** paragraph **41.2(75)"c"**:

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

ITEM 58. Amend subrule 41.2(81) as follows:

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) to be a physician who:

a. No change.

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for uses in the oral administration of less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131~~,~~ or 41.2(82) or ~~before May 3, 2006, who meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or meets~~ equivalent NRC or agreement state requirements; or

c. (1) No change.

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"* 41.2(75), 41.2(81) or 41.2(82)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or~~ equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. to 6. No change.

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81)~~,~~ or 41.2(82)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, 35.392, or 35.394, or~~ equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131.

ITEM 59. Amend subrule 41.2(82) as follows:

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) to be a physician who:

a. No change.

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or~~ meets equivalent NRC or agreement state requirements; or

c. (1) No change.

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"*41.2(75) or 41.2(82)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or~~ equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. to 5. No change.

6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390 or 35.394, or~~ equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 ~~Gigabecquerels~~ gigabecquerels) of sodium iodide I-131.

ITEM 60. Amend subrule 41.2(87) as follows:

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed by-product material or any therapeutic dose of radiation from by-product material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

~~*a.*~~ *b.* Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) and (2) No change.

(3) For gamma stereotactic radiosurgery: ~~target coordinates, collimator size, plug pattern, and total dose~~ the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) No change.

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, dose per fraction, number of fractions and total dose; or

(6) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radioisotope, number of sources, and source strengths and dose; and

2. No change.

(7) For therapeutic use of radiation machines, see 41.3(14)~~;~~.

~~*b.*~~ *c.* Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive~~;~~.

~~*c.*~~ *d.* The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives~~;~~.

~~*d.*~~ *e.* Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41~~;~~.

~~*e.*~~ *f.* Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken~~;~~.

~~*f.*~~ *g.* ~~If, because of the emergent nature of the patient's or human research subject's condition, a delay in order to provide a written directive jeopardizes the patient's or human research subject's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's or human research subject's record. A written directive must be prepared within 48 hours of the oral directive; and~~ A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user with 48 hours of the oral revision.

~~*g.*~~ *h.* A copy of the written directive in auditable form shall be retained for three years after the date of administration.

~~*h.* A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.~~

ITEM 61. Amend subrule 41.2(89) as follows:

41.2(89) *Training for the parenteral administration of unsealed by-product material requiring a written directive.* Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

a. Is an authorized user under 41.2(69)~~,~~ for parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, for uses listed in 41.2(89), or meets~~ equivalent NRC or agreement state requirements; or

b. Is an authorized user under 41.2(70) or 41.2(73)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.690, or meets~~ equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89)*"d"*; or

c. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73)~~, or before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.690,~~ and who meets the requirements in 41.2(89)*"d"*; or

d. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

1. to 5. No change.

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, or~~ equivalent NRC or agreement state requirements, in the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 41.2(69) ~~or before May 3, 2006, meets the requirements in 10 CFR 35.390~~ must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The work experience must involve:

1. to 6. No change.

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)*"b"* or *"c,"* and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89)~~,~~ or ~~before May 3, 2006, meets the requirements in 10 CFR 35.390, or~~ equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)~~, or before May 3, 2006, meets the requirements in 10 CFR 35.390,~~ must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.

ITEM 62. Amend paragraph **45.1(1)"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~~ September 15, 2010.

The provisions of 641—Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

ITEM 63. Amend subparagraph **45.1(10)"f"(1)** as follows:

(1) Application.

1. An application for taking the examination shall be on forms prescribed and furnished by the agency along with the fee required in 641—subrule 38.8(3). The application shall be submitted only after the training requirements of 45.1(10)*"a"* and *"b"* have been completed.

2. No change.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these amendments [amendments to Chs 38 to 41, 45] is being omitted. With the exception of the change noted above, these amendments are identical to those published under Notice as **ARC 8762B**, IAB 5/19/10.

[Filed 7/14/10, effective 9/15/10]

[Published 8/11/10]

[For replacement pages for IAC, see IAC Supplement 8/11/10.]