



**Iowa Department of Public Health**  
**Promoting and Protecting the Health of Iowans**

Thomas Newton, MPP, REHS  
 Director

Chester J. Culver  
 Governor

Patty Judge  
 Lt. Governor

February 23, 2010

Terrence Reis, Deputy Director  
 Division of Materials Safety and State Agreements  
 Office of Federal and State Materials and  
 Environmental Management Programs  
 U. S. Nuclear Regulatory Commission  
 Washington, D.C. 20555-0001

Dear Mr. Reis:

Enclosed is a copy of the **proposed** revisions to the State of Iowa Radiological Health Rules, Iowa Administrative Code (IAC) 641-38(136C) General Provisions for Radiation Machines and Radioactive Materials, 641-39(136C) Licensure of Radioactive Materials, 641-40(136C) Standards for Protection Against Radiation, 641-41(136C) Use of Radionuclides in the Healing Arts, and 641-45(136C) Radiation Safety Requirements for Industrial Radiographic Operations. The proposed revisions will be made available for public comment on June 2, 2010 with a request for comments by June 22, 2010. We request NRC comments by May 21, 2010. The proposed regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC regulations.

These revisions are intended to incorporate RATS ID 2007-3, 2008-1, and 2009-1 into the Iowa Administrative Code. Please note that only compatibility categories A, B, C, and H&S were considered for these revisions. Several changes in RATS ID 2007-3 required no change to Iowa rules.

<u>ITEM</u>	<u>RATS ID</u>	<u>NRC 10 CFR PART</u>	<u>State Sections</u>
2	2007-3 and 2008-1	20.1003, 30.4, and 35.2	38.2
8	2007-3	30.15(a)(1)(viii)	39.4(3)"c"(1)
9	Comment 1 in NRC letter dated 9/16/2009	30.15(b)	39.4(3)"c"(1)8
10	2007-3	30.20(a)	39.4(3)"c"(3)
11	2007-3	31.5(b)(1)	39.4(22)"d"(2)
12	2007-3	31.12	39.4(22)"k"
13	2007-3	30.32(g) 30.32(j)	39.4(24)"g" 39.4(24)"h"
14	2007-3	32.57	39.4(29)"f"
15	2007-3	32.71(b)(8) & (c)(1)	39.4(29)"h"(2) & (3)
16 & 17	2007-3	32.72	39.4(29)"j"
18	2007-3	30.34(g) 30.34(j)	39.4(32)"e" 39.4(32)"g"
19	2007-3	30.72 Schedule C	39, Appendix G
21	2008-1	20.1201	40.15(3)
22	2007-3	20.2001(a)(4)	40.70(1)"d"

<u>ITEM</u>	<u>RATS ID</u>	<u>NRC 10 CFR PART</u>	<u>State Sections</u>
23	2007-3	20.2006(e)	40.75(4)
24	2007-3	20.2008	40.77
25	2008-1	20.2205	40.97(3)
26 & 27	2008-1	19.13	40.112(2) & (4)
28 & 29	2007-3	20, Appendix B	40, Appendix B
32	2007-3	35.100	41.2(31)
33	2007-3	35.200	41.2(33)
34	2007-3	35.204	41.2(34)
35	2007-3	35.300	41.2(37)
36	2009-1	35.50	41.2(65)"a"(2)
37, 38 & 39	2009-1	35.190	41.2(67)
40, 41, 42 & 43	2009-1	35.290	41.2(68)
44, 45 & 46	2009-1	35.390	41.2(69)
47 & 48	2009-1	35.490	41.2(70)
49 & 50	2009-1	35.491	41.2(71)
51 & 52	2009-1	35.690	41.2(73)
53 & 54	2009-1	35.51	41.2(74)
55	2009-1	35.57	41.2(75)
56, 57, 58 & 59	2009-1	35.392	41.2(81)
60, 61, 62 & 63	2009-1	35.394	41.2(82)
65, 66, 67, 68, 69 & 70	2009-1	35.396	41.2(89)

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please contact me or Randal S. Dahlin of my staff at 515-281-0419 or [rdahlin@idph.state.ia.us](mailto:rdahlin@idph.state.ia.us).

Best regards,



Melanie Rasmusson, MBA, Chief  
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RSD/rd

Enclosure

## **PUBLIC HEALTH DEPARTMENT [641]**

### **Notice of Intended Action**

Pursuant to the authority of Iowa Code section 136C.3 the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 38, “General Provisions for Radiation Machines and Radioactive Materials”, Chapter 39, “Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials”, Chapter 40, “Standards for Protection against Radiation”, Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials”, and Chapter 45, “Radiation Safety Requirements for Industrial Radiographic Operations” Iowa Administrative Code.

Items 1, 7, 20, 30, and 71 amend rules to reflect current federal regulations. Item 3 and item 4 adds electronic brachytherapy devices to rule. Item 5 removes the general license registration fee from rule and adds to the agency fee schedule. Item 6 clarifies payment requirements to obtain permits for radioactive material shipments. Item 9 resolves comment #1 in NRC letter to Melanie Rasmusson dated 09/16/2009. Item 29 corrects the location of values for Sulfur-35. Item 31 clarifies the requirement for assay of doses. Item 72 ensures proper training is completed prior to the exam. The remaining items are amended to meet Nuclear Regulatory Commission compatibility requirements.

Any interested person may make written suggestions or comments on these proposed amendments on or before . Such written materials should be directed to Chief of Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Fifth

Floor, 321 East 12<sup>th</sup> Street, Des Moines, Iowa 50319; fax (515) 281-4529; or E-mail [atostleb@idph.state.ia.us](mailto:atostleb@idph.state.ia.us) .

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

The following amendments are proposed.

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

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

Item 2. Amend subrule **38.2(136C)**, Definitions, as follows:

Amend the following definitions:

~~“Authorized medical physicist” means an individual who meets the requirements of 641—subrule 41.2(74) and 641—subrule 41.2(77); or before May 3, 2006, meets the requirements in 10 CFR 35.961(a) or (b) and 10 CFR 35.59; or is identified as an authorized medical physicist or teletherapy physicist on a specific medical license issued by this agency, the NRC, or an agreement state, a medical use permit issued by the NRC master material licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, a permit issued by an NRC or agreement state broad scope medical use licensee, or a permit issued by an NRC master material license broad scope medical use permittee.~~

“By-product material” means (1) 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) 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)(i) 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 (ii) Any material that (A) Has been made radioactive by use of a particle accelerator; and (B) 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 (i) 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 similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) 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 ~~dee~~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 byproduct 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 byproduct 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 Byproduct material set forth in this Chapter.~~

Adopt the following **new** definitions in alphabetical order:

“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 3. 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 –
7. (Industrial/Nonmedical Use) \$50 –

8. Food Sterilization \$1000 –

9. Accelerators and electronic brachytherapy units \$100 –

10. Electron Microscope \$20 –

11. Bone Densitometry \$25 –

Item 4. Amend **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 5. Amend paragraph **38.8(2)“c”** as follows:

c. Registration. Each person having generally licensed radioactive materials shall annually register with the department and pay a nonrefundable annual fee ~~of \$200~~ that shall not exceed those specified in 10 CFR 170.31. The radioactive material fee schedule is available at [www.idph.state.ia.us](http://www.idph.state.ia.us).

Item 6. Amend subparagraph **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 7. 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~~\_\_\_\_\_.

Item 8. Amend subparagraph **39.4(3)“c”(1)**, numbered list as follows:

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  $\mu$ Gy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1  $\mu$ Gy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2  $\mu$ Gy) 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.~~

Item 9. Amend subparagraph **39.4(3)“c”(1)** as follows:

8. Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph “c”(1) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct 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 paragraph “c”(1) of this section.

Item 10. 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 32.276 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.

Item 11. 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 12. Amend subrule **39.4(22)** as follows:

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 mean products originally intended for use by the general public and distributed in the late 19<sup>th</sup> and early 20<sup>th</sup> centuries, such as, not 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 byproduct 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 byproduct 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 byproduct material in accordance with the general license in 39.4(22)“k”(1) shall:

1. Notify the agency should there be any indication of possible damage to the product so that it appears it 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, 5<sup>th</sup> Floor, 321 East 12<sup>th</sup> 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 written request from the agency to provide information relating to the general license with 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 13. Amend subrule **39.4(24)** as follows:

“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 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 its 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 641-39(136C) 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 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 non-commercially transferred to members of its consortium.

Item 14. 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:

- Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;
- Details of construction and design;
- Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
- 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;

- Details of quality control procedures to be followed in the manufacture of the source;
- Description of labeling to be affixed to the source or storage container for the source;
- 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 will contain 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;

- 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
- 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 shall affix 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 shall conduct a leak test on sealed sources in accordance with 10 CFR Part 32.59.

Item 15. Amend subparagraph **39.4(29)“h”(2)** as follows:

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

1. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
2. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
3. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.
4. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
5. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.
6. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.
7. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.
8. Cobalt-57 in units not exceeding 10 microcuries (370kBq) each.

Item 16. Amend subparagraph **39.4(29)“j”(1)**, numbered list as follows:

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 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.

Item 17. Amend subparagraph **39.4(29)“j”(2)**, numbered list 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. ~~Shall permit~~ The actions authorized in 39.4(29)“j”(2)“1” and “2” that are permitted in spite of more restrictive language in license conditions.

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
- The permit issued by a licensee or NRC master materials permittee of broad scope or the 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 18. Amend subparagraph **39.4(32)** “**e**” as follows:

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 641-41.2(34). The licensee shall record the results of each test and retain each record for 3 years after the record is made.

ef. Each general licensee that is required to register by 39.4(21) or (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.~~(4) The notification specified in 39.4(32)“~~ef~~” 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 non-commercial transfer to medical use licensees in its 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 non-commercial transfer to medical use licensees in its 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 non-commercial distribution to members of its consortium.

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for non-commercial distribution to members of its 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 non-commercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

1. an authorized nuclear pharmacist that 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 641-41.2(11).

(4) A pharmacy, authorized under 39.4(29)“j” to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements in 39.4(29)“j”(2)5.

Item 19. Amend **39-Appendix G** as follows:

#### CHAPTER 39—APPENDIX G

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF  
THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive Material	Release Fraction	Quantity (curies)
Promethium-147	.01	4,000
<u>Radium-226</u>	<u>0.001</u>	<u>100</u>
Ruthenium-106	.01	200

Item 20. 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~~\_\_\_\_\_.

Item 21. Amend subrule **40.15(3)** as follows:

~~40.15(3) The assigned deep dose equivalent must be for the portion 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. 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 22. Amend paragraph **40.70(1)“d”** as follows:

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

Item 23. Amend subrule **40.75(4)** as follows:

40.75(4) Any licensee shipping byproduct material as defined in sections (3) and (4) of the definition of Byproduct 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 24. Amend **40.77(136C)** as follows:

641-40.77(136C) Disposal of certain byproduct material

40.77(1) Licensed material as defined in sections (3) and (4) of the definition of Byproduct material set forth in 641-Chapter 38 may be disposed of in accordance with 10 CFR

Part 61, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirement of 641-40.75(136C).

40.77(2) A licensee may dispose of byproduct material, as defined in sections (3) and (4) of the definition of Byproduct 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 25. Amend subrule **40.97(3)** as follows:

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

Item 26. Amend subrule **40.112(2)** as follows:

40.112(2) ~~Each licensee or registrant shall advise each worker annually of the worker's dose as shown in records maintained by the licensee or registrant pursuant to 40.86(136C).~~ 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 40.86(136C). The licensee or registrant shall provide an annual report to each individual monitored under 40.37(136C) 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 his or her annual dose report.

Item 27. Amend subrule **40.112(4)** as follows:

40.112(4) When a licensee or registrant is required pursuant to 40.96(136C), 40.97(136C), or 40.98(136C) to report to the ~~A~~gency 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~~ his or her 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 ~~A~~gency.

Item 28. Amend **Chapter 40 Appendix B, List of Elements** as follows:

Name	Symbol	Number
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
<u>Nitrogen</u>	<u>N</u>	<u>7</u>
Osmium	Os	76
<u>Oxygen</u>	<u>O</u>	<u>8</u>

Item 29. Amend **Chapter 40, Appendix B** as follows:

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col.1	Col.2	Col.3	Col.1	Col.2	Monthly Average Concentration (µCi/ml)
		Oral Ingestion ALI (µCi)	INHALATION ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	
<u>7 Nitrogen-13<sup>2</sup></u>	<u>Submersion<sup>1</sup></u>			<u>4E-6</u>		<u>2E-8</u>	
<u>8 Oxygen-15<sup>2</sup></u>	<u>Submersion<sup>1</sup></u>			<u>4E-6</u>		<u>2E-8</u>	
16 Sulfur-35	Vapor	<del>1E+4</del>	<del>6E-6</del>	<del>2E-8</del>	<u>6E-6</u>	<u>2E-8</u>	

Item 30. Amend subrule **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 July 9, 2008\_\_\_\_\_.

Item 31. 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);~~

eb. 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;

dc. 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

ed. Retain a record of the assays required by 41.2(19)“a” for three years. To satisfy this requirement, the record shall contain the:

Item 32. 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 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 a PET radioactive drug producer licensed pursuant to 641-39.4(24)“h” or equivalent NRC or agreement state requirements.

b. Excluding 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~~

Item 33. Amend subrule **41.2(33)** as follows:

41.2(33) Use of ~~radiopharmaceuticals, generators, and reagent kits~~ unsealed byproduct 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 byproduct material prepared for medical use that is either:

a. 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 641-39.4(24)“h” or equivalent NRC or agreement state requirements;

b. ~~Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69), or an individual under the~~

supervision of either as specified in 41.2(11); Excluding 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;

Item 34. Amend subrule **41.2(34)** as follows:

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

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

(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 in each eluate or extract.

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 megabecquerels 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.”(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34)“a”(2).

Item 35. Amend subrule **41.2(37)** as follows:

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

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

(1) A manufacturer or preparer licensed under 641.39.4(29)“j” or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641-39.4(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 Excluding 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

Item 36. Amend subparagraph **41.2(65)“a”(2), numbered list** as follows:

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

Item 37. 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 38. Amend paragraph **41.2(67)“c”, numbered list** as follows:

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 39. 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 40. Amend subrule **41.2(68)** 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 41. 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;”<sub>2</sub>, 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 42. Amend paragraph **41.2(68)“c”(1), numbered list** as follows:

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

Item 43. 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)<sub>2</sub> ~~or 41.2(69) and 41.2(68)“c”(1)“2;”<sub>2</sub>, seventh bulleted paragraph~~ or 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 44. Amend subparagraph **41.2(69)“b”(1), numbered list** as follows:

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 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;”, ~~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 Ggigabecquerels) of sodium iodide I-131, for which a written directive is required;
  - Oral administration of greater than 33 millicuries (1.22 Ggigabecquerels) 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 45. 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), 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 46. Amend subrule **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 Ggigabecquerels) or quantities greater than 33 millicuries (1.22 Ggigabecquerels), see 41.2(81) or 41.2(82).

Item 47. Amend subrule **41.2(70)** 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 48. Amend subparagraph **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. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70), 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), 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), 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 49. 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 50. 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), 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 51. Amend subrule **41.2(73)** 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 52. 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. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73), 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), 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), 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 53. 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. 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

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 54. 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<sub>7</sub>”<sub>a</sub> 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 55. Amend subrule **41.2(75)** as follows:

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 56. 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 ~~G~~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 ~~G~~gigabecquerels) to be a physician who:

Item 57. Amend paragraph **41.2(81)“b”** as follows:

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 ~~G~~gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 ~~G~~gigabecquerels) of sodium iodide I-131, 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

Item 58. Amend subparagraph **41.2(81)“c”(2)** as follows:

(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 ~~G~~gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 ~~G~~gigabecquerels) of sodium iodide I-131. The work experience must involve:

Item 59. Amend subparagraph **41.2(81)“c”(3)** as follows:

(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 ~~G~~gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 ~~G~~gigabecquerels) of sodium iodide I-131.

Item 60. 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 ~~G~~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 ~~G~~gigabecquerels) to be a physician who:

Item 61. Amend paragraph **41.2(82)“b”** as follows:

b. Is an authorized user under 41.2(69)“a” or “b” for oral administration of greater than 33 millicuries (1.22 ~~G~~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

Item 62. Amend subparagraph **41.2(82)“c”(2)** as follows:

(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 Ggigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
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 Ggigabecquerels) of sodium iodide I-131; and

Item 63. Amend subparagraph **41.2(82)“c”(3)** as follows

(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) of sodium iodide I-131.

Item 64. 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 byproduct material or any therapeutic dose of radiation from byproduct 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. 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.

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

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(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) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(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. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose);

(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;

~~e~~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 byproduct 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. 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.

gh. 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 byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.~~

Item 65. Amend paragraph **41.2(89)“a”** as follows:

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

Item 66. Amend paragraph **41.2(89)“b”** as follows:

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

Item 67. Amend paragraph **41.2(89)“c”** as follows:

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

Item 68. Amend paragraph **41.2(89)“d”** as follows:

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 and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

Item 69. Amend subparagraph **41.2(89)“d”(2)** as follows:

(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:

Item 70. Amend subparagraph **41.2(89)“d”(3)** as follows:

(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 byproduct 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 71. 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~~\_\_\_\_\_.

Item 72. Amend subparagraph **45.1(1)“f”(1)** as follows:

f. Applications and examinations.

(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—38.8(3). The application shall be submitted only after the training requirements of 45.1(10)“a” and “b” have been completed.