ARC 7792B

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials," and Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," Iowa Administrative Code.

Items 1 and 13 amend rules to reflect current federal regulations. 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 June 9, 2009. 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 12th Street, Des Moines, Iowa 50319; fax (515)281-4529; or E-mail atostleb@idph.state.ia.us.

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

The following amendments are proposed.

ITEM 1. 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 ~~July 9, 2008~~ September 2, 2009.

ITEM 2. Amend subparagraph **39.4(3)"a"(2)** as follows:

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3)*"a"*(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, or any agreement state ~~or licensing state~~, except in accordance with a specific license issued pursuant to ~~39.4(29) or the general license provided in 39.4(90)~~ 10 CFR 32.11.

ITEM 3. Amend subparagraph **39.4(3)"a"(5)** as follows:

(5) A manufacturer, processor, or producer of a product or material ~~in an agreement state~~ is exempt from the requirements for a license and from these rules to the extent that the manufacturer, processor, or producer transfers radioactive material contained in a product or material in concentrations not in excess of the requirements in Appendix A of this chapter and introduced into the product or material by a licensee holding a specific license issued by ~~an agreement state or~~ the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

ITEM 4. Amend paragraph **39.4(3)"b"** as follows:

b. Exempt quantities.

(1) Except as provided in 39.4(3)*"b"*(3), ~~and~~ (4), and (5), any person is exempt from the requirements for a license and from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under ~~the~~ a general license ~~issued for manufacture of devices and equipment under special license from NRC~~ is exempt from the

requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material. ~~Such exemption does not apply for radium-226.~~

(3) This paragraph (39.4(3)*"b"*) does not authorize for purposes of commercial distribution the production, packaging, ~~or~~ repackaging or transfer of radioactive material ~~for purposes of commercial distribution,~~ or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32, ~~or by the agency pursuant to 39.4(29)*"b,"*~~ which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3)*"b"* or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Appendix B of this chapter, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

ITEM 5. 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. and 2. No change.

~~3. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

~~4.~~ 3. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007.

~~5. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.~~

~~6.~~ 4. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007.

~~7. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.~~

~~8.~~ 5. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

- 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
- 1 microcurie (37 kBq) of cobalt-60;
- 5 microcuries (185 kBq) of nickel-63;
- 30 microcuries (1.11 MBq) of krypton-85;
- 5 microcuries (185 kBq) of cesium-137; and
- 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. For purposes of ~~39.4(3)*"c"*(1)"8,"~~ 39.4(3)*"c"*(1)"5," the term "electron tubes" ~~include~~ includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

~~9.~~ 6. Ionizing radiation measuring instruments, for purposes of internal calibration or standardization, containing one or more sources of radioactive material, provided that:

- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each device contains no more than ten exempt quantities. For purposes of this requirement, a device's source(s) may contain either one type of or different types of radionuclides, and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or
- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under ~~39.4(3)*"c"*(1)"9."~~ 39.4(3)*"c"*(1)"6."

~~10. Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 l) per hour.~~

7. Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

ITEM 6. Rescind and reserve subparagraph **39.4(3)"c"(4)**.

ITEM 7. Amend subparagraph **39.4(22)"d"(3)**, numbered list, as follows:

1. to 7. No change.

8. Shall transfer or dispose of the device containing radioactive material only by export as provided by 39.4(22)*"d"*(3)"7," by transfer to another general licensee as authorized in 39.4(22)*"d"*(3)"9," to a person authorized to receive the device by a specific license issued by the agency, the NRC, an agreement state or a licensing state whose specific license authorizes the person to receive the device or which authorizes waste collection, or as otherwise approved under 39.4(22)*"d"*(3):

- Shall furnish a report to this agency within 30 days after the transfer of a device to a specific licensee or export. The report must contain the identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address and license number of the person receiving the device (license number not applicable if device is exported); and the date of the transfer;
- Shall obtain written agency approval before transferring the device to any other specific licensee not specifically identified in 39.4(22)*"d"*; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

—Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

—Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by 39.4(22)*"d"*(3)"1") so that the device is labeled in compliance with 641—40.63(136C) of these rules; however the manufacturer, model number, and serial number must be retained;

—Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak-testing procedures); and

—Reports the transfer under 39.4(22)*"d"*(3)"8" of this chapter.

9. to 15. No change.

ITEM 8. Rescind and reserve paragraphs **39.4(29)"a"** and **"c."**

ITEM 9. Amend subparagraph **39.4(29)"j"(2)**, numbered list, as follows:

1. to 4. No change.

5. Shall provide to the agency a copy of each individual's: ~~certification by the Board of Pharmaceutical Specialties, the NRC, or agreement state license, or the permit issued by a licensee of~~

~~broad scope, and a copy of the 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.~~

● 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

● 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 10. Amend paragraph **39.4(29)"l,"** introductory paragraph, as follows:

l. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration, transmission, or reference source or for the uses listed in 641—subrules 41.2(41), 41.2(43), ~~and~~ 41.2(49), and 41.2(88) will be approved if:

ITEM 11. Rescind and reserve paragraph **39.4(29)"n."**

ITEM 12. Amend subparagraph **39.4(90)"a"(6)** as follows:

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)*"a"* except by transfer to a person~~:~~ specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material.

~~1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or~~

~~2. Exempt from the requirements for a license for such material under 39.4(3)*"a."*~~

ITEM 13. 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 ~~May 3, 2006~~ September 2, 2009.

ITEM 14. Amend subrule 41.2(19) as follows:

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

a. No change.

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); ~~and~~

c. 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. 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

~~*d.*~~ *e.* 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 15. Amend paragraph **41.2(27)"a"** as follows:

a. The licensee may authorize the release from its control of any individual who has been administered ~~radiopharmaceuticals~~ unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes

methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

ITEM 16. Amend paragraph **41.2(30)"a,"** introductory paragraph, as follows:

a. A licensee may hold radioactive material with a physical ~~half-lives~~ half-life of less than or equal to 120 days~~, except for Cobalt-57~~ for decay-in-storage before disposal ~~in ordinary trash and is exempt from the requirements of 641—subrule 40.70(1)~~ without regard to its radioactivity if the licensee:

ITEM 17. Amend subparagraphs **41.2(57)"a"(1)** and **(2)** as follows:

(1) The system ~~shall~~ must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration ~~shall~~ must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system ~~shall~~ must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system ~~shall~~ must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must ~~have indicated~~ indicate that the calibration factor of the licensee's system ~~had~~ has not changed by more than 2 percent. The licensee ~~shall~~ may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

ITEM 18. Amend paragraph **41.2(57)"b"** as follows:

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57)*"a."* This comparison ~~shall~~ must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system ~~shall~~ may be the same system used to meet the requirement in 41.2(57)*"a."*

ITEM 19. Amend subparagraph **41.2(67)"a"(1)** as follows:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies~~, which include the topics listed in~~ as described in 41.2(67)*"c"*(1)"1" and "2"; and

ITEM 20. Amend subparagraph **41.2(68)"a"(1)** as follows:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies ~~that include the topics listed in~~ as described in 41.2(68)*"c"*(1)"1" and "2"; and

ITEM 21. 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 before May 3, 2006, meets the requirements in 10 CFR 35.490 or 35.491, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in ~~41.2(71)*"a"* and *"b"*~~ 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.