May 2009 rule changes
RATS ID 2007-2

Item 1. Amend subrule **39.4(3)**, paragraph **"a,"** subparagraph **(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)~~.

Item 2. Amend subrule **39.4(3)**, paragraph **"a,"** subparagraph **(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 3. Amend subrule **39.4(3)**, paragraph **"b,"** subparagraph **(1),** as follows:

(1) Except as provided in 39.4(3)*"b"*(3), ~~and~~ (4), and (5) any person is exempt 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.

Item 4. Amend subrule **39.4(3)**, paragraph **"b,"** by adopting **new** subparagraph **(5),** as follows:

(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. Rescind subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1),** the third numbered paragraph in its entirety and reserve.

Item 6. Amend subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1),** the fourth numbered paragraph as follows:

4. 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.

Item 7. Rescind subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1)**, the fifth numbered paragraph in its entirety and reserve.

Item 8. Amend subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1)**, the sixth numbered paragraph as follows:

6. 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.

Item 9. Rescind subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1)**, the seventh numbered paragraph in its entirety and reserve.

Item 10. Rescind subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1)**, the tenth numbered paragraph in its entirety and reserve.

Item 11. Amend subrule **39.4(3)**, paragraph **"c,"** subparagraph **(1)**, adopting a **new** numbered paragraph as follows:

(11) 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 12. Rescind subrule **39.4(3)**, paragraph **"c,"** subparagraph **(4)**, in its entirety

Item 13. Amend subrule **39.4(22)**, paragraph **"d,"** subparagraph **(3)**, the eighth numbered paragraph as follows:

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 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 40.63 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.

Item 14. Rescind subrule **39.4(29)**, paragraph **"a," "c,"** and **"n,"** in their entirety and reletter remaining paragraphs.

Item 15. Amend subrule **39.4(90)**, paragraph **"a,"** subparagraph **(6),** the first and second numbered paragraphs as follows:

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."*~~

May 2009 rule changes
RATS ID 2007-1

Item 16. Amend subrule **39.4(29)**, paragraph **"j,"** subparagraph **(2)**, the fifth numbered paragraph as follows:

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 41.2(78) "a" with the written attestation signed by a preceptor as required by 41.2(78) "c"; or
- The NRC or Agreement State license; or
- The permit issued by a licensee of broadscope; 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 17. Amend subrule **39.4(29)**, paragraph **"l,"** 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 18. Amend subrule **41.2(19)** by adopting **new** paragraph **"d"** and renumbering paragraph **"e,"** follows:

d. Unless otherwise directed by the authorized user, a licensee may 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.

~~*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:

Item 19. Amend subrule **41.2(27)**, paragraph **"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). (The current revision of 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 20. Amend subrule **41.2(30)**, paragraph **"a,"** as follows:

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

Item 21. Amend subrule **41.2(57)**, paragraph **"a,"** subparagraphs **(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 that the calibration factor of the licensee's system had 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 22. Amend subrule **41.2(57)**, paragraph **"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 23. Amend subrule **41.2(67)**, paragraph **"a,"** subparagraph **(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, as described in ~~which include the topics listed in~~ 41.2(67)*"c"*(1)"1" and "2"; and

Item 24. Amend subrule **41.2(68)**, paragraph **"a,"** subparagraph **(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 as described in ~~that include the topics listed in~~ 41.2(68)*"c"*(1)"1" and "2"; and

Item 25. Amend subrule **41.2(71**), paragraph **"b,"** subparagraph **(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"*~~ "b" (1) and "b" (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Public Health Department [641]

Notice of Intended Action

Pursuant to the authority of Iowa Code sections 136B.4, 136C.3 and 136D.7 the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 38, "General Provision of 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 Machine and Certain Uses of Radioactive Materials," Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists," Chapter 44, "Minimum Requirements for Radon Mitigation," and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following paragraphs itemize the proposed changes:

Items 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25 are amended to meet Nuclear Regulatory Commission compatibility requirements.

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on April 29, 2008. Such written materials should be directed to Chief of Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319; Fax (515) 281-4529; or Email atostleb@idph.state.ia.us.

Item 1 and 2 amends to add new subparagraph for person(s) exempt to meet Nuclear Regulatory Commission compatibility requirements.

Item 3, 5, 7 and 8 rescinds subparagraph to meet Nuclear Regulatory Commission compatibility requirements.

Item 4 and 6amends subparagraph to add manufactured date to meet Nuclear Regulatory Commission compatibility requirements.

Item 9 adds new paragraph in order to meet Nuclear Regulatory Commission compatibility requirements.

Item 10 rescinds subparagraph to meet Nuclear Regulatory Commission compatibility requirements.

Item 11 adds language for the transfer or disposal of devices containing radioactive materials to meet Nuclear Regulatory Commission compatibility requirements.

Item 12 rescinds paragraphs to meet Nuclear Regulatory Commission compatibility requirements.

Item 13 removes requirement for transfer or disposal in subparagraphs to meet Nuclear Regulatory Commission compatibility requirements.

Item 14 and 15 removes language from subparagraphs to meet Nuclear Regulatory Commission compatibility requirements.

Item 16 adds subrule and language to include transmission to meet Nuclear Regulatory Commission compatibility requirements.

Item 17 amends requirements for individual