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C. Earl Hunter, Commissioner

Promoting and protecting the health of the public and the environment.

December 22, 2010

Cynthia Carpenter, Deputy Director
Division 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 Ms. Carpenter:

Enclosed is a copy of the final revisions to the South Carolina Radiological Health's Radioactive Materials Regulations 61-63, Title A (final date of November 24, 2010). The final regulations are identified by strike through /underline text and correspond to the following equivalent amendments to NRC's regulations.

<u>Rats ID</u>	<u>Title</u>	<u>State Section</u>
• 2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications	RHA Parts II & IV
• 2007-2	Exemptions From Licensing, General Licenses and Distribution	RHA Part II
• 2009-1	Medical Use of Byproduct Material - Authorized User Clarification	RHA Part IV

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 Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (803) 545-4400 or Melinda W. Bradshaw of my staff at (803) 545-4577 or bradshmw@dhec.sc.gov.

Sincerely,

Aaron A. Gantt, Bureau Chief
Bureau of Radiological Health
Department of Health and
Environmental Control

Enclosures:
As stated

TEXT OF REVISIONS
R.61-63, Radioactive Materials, Title A
November 10, 2010

~~Indicates Matter Stricken~~

Indicates New Matter

Text:

Revise 2.4.2.3.7.2 and add new subitems to read:

2.4.2.3.7.2 Shall obtain written Departmental approval before transferring the device to any other specific licensee not specifically identified in RHA 2.4.2.3.7; 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:

2.4.2.3.7.2.1 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;

2.4.2.3.7.2.2 Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RHA 2.4.2.3.1) so that the device is labeled in compliance with RHA 3.24; however the manufacturer, model number, and serial number must be retained;

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

2.4.2.3.7.2.4 Reports the transfer under RHA 2.4.2.3.7.1.

Revise 2.7.5.2.5 and add new subitems to read:

~~2.7.5.2.5 Shall provide to the Department 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 paragraphs 2.7.5.2.2.1 and 2.7.5.2.2.3 of this section, the individual to work as an authorized nuclear pharmacist.~~

2.7.5.2.5.1 Certification by a specialty board whose process has been recognized by the NRC or an Agreement State as specified in RHA 4.22.1 of this regulation with the written attestation signed by a preceptor as required by RHA 4.22.3 ; or

2.7.5.2.5.2 The NRC or Agreement State license; or

2.7.5.2.5.3 The permit issued by a licensee of broad scope; and

2.7.5.2.5.4 State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under RHA 2.7.5.2.2.1 and 2.7.5.2.2.3, the individual to work as an authorized nuclear pharmacist.

Revise 2.7.7.1 introductory; subitems 2.7.7.1.1, 2.7.7.1.2 and 2.7.7.1.3 remain the same:

2.7.7.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part IV of these regulations for use as a calibration, transmission, or reference source or for the uses listed in RHA 4.46, 4.56, ~~and 4.58~~ and 4.88 of Part IV of these regulations will be approved if:

Revise section 2.20.2.1.1 to read:

2.20.2.1.1 Except as provided in ~~2.20.2.6.2~~ RHA 2.20.2.1.3 and 2.20.2.1.4, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material ~~introduced in concentrates~~ concentrations not in excess of those listed in Schedule C of this part.

Revise section 2.20.2.1.2 to read:

~~2.20.2.1.2 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 2.20.2.6 or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to 2.7.2 of the general license provided in 2.21. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.~~

Add new section 2.20.2.1.3 to read:

2.20.2.1.3 A manufacturer, processor, or producer of a product or material is exempt from this part to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule C of this part and introduced into the product or material by a licensee holding a specific license issued by the NRC 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.

Add new section 2.20.2.1.4 to read:

2.20.2.1.4 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 this section or equivalent NRC or Agreement State regulations, except in accordance with a license issued under RHA 2.7.2.

Revise section 2.20.2.2 introductory; subitems 2.20.2.2.1, 2.20.2.2.1.1, 2.20.2.2.1.1.2, 2.20.2.2.1.1.3, 2.20.2.2.1.4, 2.20.2.2.1.6 and 2.20.2.2.1.7 remain the same:

2.20.2.2 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 these regulations to the extent that he receives, possesses, uses, ~~and~~ transfers, owns, or acquires the following products:⁶

Revise section 2.20.2.2.1.5 to read:

2.20.2.2.1.5 20 microcuries of Promethium-147 per watch hand or 40 microcuries of Promethium-147 per other timepiece hand and;

Revise section 2.20.2.2.1.8 to read:

2.20.2.2.1.8 1 microcurie (37 kBq) of Radium-226 per timepiece in timepieces acquired manufactured prior to ~~the effective date of this regulation~~ November 30, 2007.

Remove text of section 2.20.2.2.2 and reserve section to read:

~~2.20.2.2.2 Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of Promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing Promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber. Reserved.~~

Revise section 2.20.2.2.3 to read:

2.20.2.2.3 Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

Remove the text of section 2.20.2.2.4 and reserve section to read:

~~2.20.2.2.4 Automobile shift quadrants containing not more than 25 millicuries of tritium. Reserved.~~

Revise section 2.20.2.2.5 to read:

2.20.2.2.5 Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

Revise text of section 2.20.2.2.6 and reserve section to read:

~~2.20.2.2.6 Thermostat dials and points containing not more than 25 millicuries of tritium per thermostat.~~ Reserved.

Revise 2.20.2.2.8 introductory; subitems 2.20.2.2.8.1 through 2.20.2.2.8.3 remain the same:

2.20.2.2.8 Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of ~~by-product~~ radioactive material; provided that:

Revise section 2.20.2.2.9 to read:

~~2.20.2.2.9 Spark gap irradiators containing not more than 1 microcurie of Cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour. (11.4 liters per hour). Ionization chamber smoke detectors containing not more than 1 microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.~~

Revise section 2.20.2.5.1 to read:

2.20.2.5.1 Except as provided in subparagraphs 2.20.2.5.3 ~~and 2.20.2.5.4 through 2.20.2.5.5~~, any person is exempt from these regulations 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 RHA 2.24, Schedule B.

Revise section 2.20.2.5.5 to read:

~~2.20.2.5.5 Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing Scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured or imported in accordance with the specifications contained in a specific license issued by the Agency of any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Section 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing Scandium-46. 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 RHA 2.24, Schedule B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

Remove the text of section 2.20.2.6, to include subitems, and reserve section to read:

2.20.2.6 ~~Exempt Concentrations Reserved.~~

~~2.20.2.6.1 Except as provided in 2.20.2.6.2, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrates not in excess of those listed in Schedule C of this part.~~

~~2.20.2.6.2 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 2.20.2.6 or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to 2.7.2 of the general license provided in 2.21.~~

Revise section 2.21.1.5 to read:

2.21.1.5 The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person (i) specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material, or (ii) ~~exempt from the requirements for a license for such material under paragraph 2.20.2.1.~~

Revise section 4.20.1.2.2.2 to read:

4.20.1.2.2.2 In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in RHA 4.23, 4.39 or RHA 4.43.

Revise section 4.21.1.2.2 to read:

4.21.1.2.2 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 RHA 4.23, 4.54 and or 4.74; and

Revise section 4.21.3 to read:

4.21.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA ~~4.21.1 or 4.21.2~~ 4.21.4 and 4.21.1.1 and 4.21.1.2 or 4.21.2 and

4.21.4 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 RHA 4.21 or ~~4.21.2~~ 4.23, 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

Add section 4.23.3 to read:

4.23.3 Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC or Agreement State licenses for the same uses for which these individuals are authorized.

Revise section 4.32.1 footnote 1 to read:

⁴~~Department Regulatory Guide “Release of Patients Administered Radioactive Materials”¹~~The current revision of NUREG-1556, Vol. 9, “Consolidated Guidance About Medical Licenses” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

Revise section 4.34.1 to read; subitems 4.34.1.1 and 4.34.1.2 remain the same:

4.34.1 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it--

Revise section 4.36.1.1 to read:

4.36.1.1 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 that includes the topics listed in paragraphs ~~4.36.2 and 4.36.3~~ through 4.36.3.2.6 of this section; and

Revise section 4.36.2 to read:

4.36.2 Is an authorized user under RHA 4.39 or 4.43 or equivalent NRC requirements; or ~~4.36.3--~~

~~Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include--~~

Add section 4.36.3 to read:

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

Revise section 4.36.3.2 to read; subitems 4.36.3.2.1 through 4.36.3.2.6 remain the same:

4.36.3.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, involving--

Revise section 4.36.4 and renumber section item to 4.36.3.3 to read:

4.36.4.3.3 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA ~~4.36.4~~ 4.36.1.1 or 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35.

Revise section 4.39.1.1 to read:

4.39.1.1 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 includes the topics listed in paragraphs RHA 4.39.3 through 4.39.3.2.7; and ~~4.39.4 of this section~~; and

Revise 4.39.3.2 introductory; subitems 4.39.3.2.1 through 4.39.3.2.7 remain the same:

4.39.3.2 Work experience, under the supervision of an authorized user, who meets the requirements in RHA 4.23, 4.39 or ~~4.39.3.2.7~~, and 4.43 and 4.39.3.2.7 or equivalent NRC requirements, involving--

Revise section 4.39.4 and renumber it to section 4.39.3.3 to read:

4.39.4.3.3 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7, or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.39.1 or 4.39.3 through 4.39.3.2.7 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35 and 4.37.

Revise section 4.43.2.2 introductory; subitems 4.43.2.2.1 through 4.43.2.2.7.4 remain the same:

4.43.2.2 Work experience, under the supervision of an authorized user who meets the requirements in RHA 4.43.1, ~~4.43.2~~ 4.23, 4.43, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages in the same dosage category or categories (i.e., RHA ~~4.43.2.2.7.1, 4.43.2.2.7.2, 4.43.2.2.7.3 or 4.43.2.2.7.4~~) as the individual requesting authorized user status. The work experience must involve--

Revise section 4.43.3 to read:

4.43.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.43.1 and 4.43.2.2.7 or 4.43.2 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.40. The written ~~certification~~ attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, or equivalent NRC requirements. The preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages in the same dosage category or categories (i.e., RHA ~~4.43.2.2.7.1, 4.43.2.2.7.2, 4.43.2.2.7.3, or 4.43.2.2.7.4~~) as the individual requesting authorized user status.

Revise section 4.43.4.3 introductory; subitems 4.43.4.3.1 through 4.43.4.3.6 remain the same:

4.43.4.3 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.4 or equivalent NRC or Agreement State requirements, in the parenteral administration, for which a written directive is required, of 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. A supervising authorized user who meets the requirements in RHA 4.43 must have experience in administering dosages as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4. The work experience must involve--

Revise section 4.43.4.4 to read:

4.43.4.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.4.1.1 and 4.43.4.1.2 of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.4, or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirements in RHA 4.43, must have experience in administering dosages as specified in RHA 4.43.2.2.7.3 and/or RHA 4.43.2.2.7.4.

Revise section 4.44.1.4; subitems 4.44.1.4.1 through 4.44.1.4.6 remain the same:

4.44.1.4 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, ~~4.43.1~~, ~~RHA 4.43.2~~, RHA 4.44, RHA 4.45, or equivalent NRC requirements. A supervising authorized user who meets the requirements in RHA 4.43.2 must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2. The work experience must involve--

Revise section 4.44.1.5 to read:

4.44.1.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.44.1.3 and 4.44.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written ~~certification~~ attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, ~~4.43.1~~, ~~4.43.2~~, 4.44, 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirement in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2.

Revise section 4.45.1.4 introductory; subitems 4.45.1.4.1 through 4.45.1.4.6 remain the same:

4.45.1.4 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, ~~4.43.1~~, ~~4.43.2~~, 4.45, or equivalent NRC requirements. A supervising authorized user, who meets the requirements in RHA 4.43.2, must also have experience in administering dosages as specified in RHA 4.43.2.2.7.2. The work experience must involve--

Revise section 4.45.1.5 to read:

4.45.1.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.45.1.3 and 4.45.1.4 and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under RHA 4.40. The written ~~certification~~ attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, RHA 4.45 or equivalent NRC requirements. A preceptor authorized user, who meets the requirements in RHA 4.43.2, must have experience in administering dosages as specified in RHA 4.43.2.2.7.2.

Revise section 4.54.1.2.2; subitems 4.54.1.2.2.1 through 4.54.1.2.2.6 remain the same:

4.54.1.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements at a medical institution, involving--

Revise section 4.54.1.3

4.54.1.3 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC 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 RHA 4.54.1.2.2; and

Revise section 4.54.1.4 to read:

4.54.1.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.54.1.1 or 4.54.1.2 and RHA 4.54.1.3 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46.

Revise section 4.55.1.4 to read:

4.55.1.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.54, 4.55, or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.55.1.1 and 4.55.1.2 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Revise 4.74.1.2.2; subitems 4.74.1.2.2.1 through 4.74.1.2.2.6 remain the same:

4.74.1.2.2 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.74 or equivalent NRC requirements at a medical institution, involving--

Revise section 4.74.1.3 to read:

4.74.1.3 Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RHA 4.23, 4.74 or equivalent NRC 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 RHA 4.74.1.2.2; and

Revise section 4.74.1.4 to read:

4.74.1.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.74.1.1.1, or 4.74.1.2 and 4.74.1.3 and 4.74.1.5 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 ~~certification~~ attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.74 or equivalent NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.