From: "Pearce O'Kelley" <OKELLETP@dhec.sc.gov>
To: <KXS@NRC.GOV>, <SWM@NRC.GOV>
Date: 05/07/2007 10:56:34 AM
Subject: Request for Review of Proposed regulation revision

Attached for your consideration is a letter requesting review of proposed revisions to SC Regulation R61-63, Radioactive Materials along with the proposed revisions. Please advise if additonal information is needed.

CC: "Melinda W. Bradshaw" <BRADSHMW@dhec.sc.gov>, "Mary Fechtel" <FECHTEMW@dhec.sc.gov>, "Aaron Gantt" <GANTTAA@dhec.sc.gov>, "Jim Peterson" <PETERSJK@dhec.sc.gov>

Mail Envelope Properties (463F3E16.F55 : 6 : 57173)

Subject:	Request for Review of Proposed regulation revision
Creation Date	05/07/2007 10:55:39 AM
From:	"Pearce O'Kelley" <OKELLETP@dhec.sc.gov>
Created By:	OKELLETP@dhec.sc.gov

Recipients

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TWGWPO02.HQGWDO01
KXS (Kathleen Schneider)

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MESSAGE	218	05/07/2007 10:55:39 AM
nrcreview.doc	21504	
61-63 revisions 07.doc	101376	
Mime.822	170285	

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Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
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Security:	Standard

Junk Mail Handling Evaluation Results

Message is eligible for Junk Mail handling
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Junk Mail handling disabled by User
Junk Mail handling disabled by Administrator
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Scott M. Moore, 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 Mr. Moore,

Enclosed is a copy of the revisions to the proposed South Carolina Radiological Health Rules R61-63, Radioactive Materials. The proposed revisions will be made available for public comment on June 22, 2007 with a request for comments by July 30, 2007. We request NRC's comments by July 30, 2007. The proposed regulations are identified by line-in/line-out text (or similar identification) and correspond to the following equivalent amendments to NRC's regulations.

Rats ID	**Title**	**State Section**
2001-1	Portable Gauges	Part II
2005-2	Recognition of Specialty Boards	Part IV
2005-1	Security Requirements for Portable Gauges	Part II
2006-1	Minor Amendments- Parts	Parts II, 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 Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at 803-545-4420 or Jim Peterson of my staff at 803-545-4407or Petersjk@dhec.sc.gov.

Sincerely,

Aaron Gantt, Director
Bureau of Radiological Health
SC Dept. Of Health & Environmental Control

Enclosures: As stated.

2.4.2.3.4 Shall maintain records showing compliance with the requirements of RHA 2.4.2.3.2 and 2.4.2.3.3. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of the persons performing, testing installation services, and removal from installation concerning the radioactive material, its shielding or containment;

The licensee shall retain these records as follows:

2.4.2.3.4.1 Each record of a test for leakage or radioactive material required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

2.4.3,2.4,2 Each record of a test of the on-off mechanism and indicator required by paragraph RHA 2.4.2.3.2 of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

2.4.2.3.4.3 Each record that is required by paragraph RHA 2.4.2.3.3 of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

2.4.2.3.7 Shall transfer or dispose of the device containing radioactive material only by export as provided by RHA 2.4.2.3.14 of this section, by transfer to another general licensee as authorized in RHA 2.4.2.3.8 or to a person authorized to receive the device by a specific license issued by this Department or by the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved under RHA 2.4.2.3.7.2. In complying with this section, the licensee:

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2.4.2.3.7.1 Shall furnish a report to the Department 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.

2.4.2.3.14 Shall not export the device containing byproduct material except in accordance with 10CFR part 110, Code of Federal Regulations;

2.4.2.3.15 Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Chief of the Bureau of Radiological Health, SC Department of Health and Environmental Control, by an appropriate method listed in RHA 1.13 of this regulation, a written justification for the request.

2.7.5.2.2.2 This individual meets the requirements specified in RHA 4.22.2, and 4.24 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

Deleted: (or, for a period of two years following the effective date of these regulations, RHA 4.86.2)

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 uses as a calibration, transmission, or reference source or for the uses listed in RHA 4.46, 4.56, and 4.58 of Part IV of these regulations will be approved if:

2.10.7 Security requirements for portable gauges.

2.10.7.1 Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

PART IV

USE OF RADIONUCLIDES IN THE HEALTH PROFESSION

4.2.26 "Preceptor" means an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

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4.2.30 "Radiation Safety Officer" means an individual who--

4.2.30.1 Meets the requirements in RHA 4.20.1 or 4.20.3 and RHA 4.24; or

4.2.30.2 Is identified as a Radiation Safety Officer on--

4.19.2 Sealed sources or devices noncommercially transferred from a Part IV licensee or an Agreement State or NRC medical use licensee,

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4.20.1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraphs 4.20.4 and 4.20.5 of this section. (The names of board certifications, which have been recognized, by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.)

Deleted: includes all of the requirements in RHA 4.20.2 and whose

Deleted: certification has been recognized by the NRC or an Agreement State;

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4.20.1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.20.1.1.1 Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

4.20.1.1.2 Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

4.20.1.1.3 Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

4.20.1.2

4.20.1.2.1 Hold a master's or doctortorate degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

4.20.1.2.2 Have 2 years of full-time practical training and/or supervised experience in medical physics

4.20.1.2.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an Agreement State; or

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 4.39 or RHA 4.43

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4.20.1.2.3 Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

4.20.2 Has completed a structured educational program consisting of both:

4.20.2.1 200 hours of classroom and laboratory, training in the following areas--

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4.20.2.1.1 Radiation physics and instrumentation;

4.20.2.1.2 Radiation protection;

4.20.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.20.2.1.4 Radiation biology; and

4.20.2.1.5 Radiation dosimetry; and

4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.21 and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements RHA 4.20.4 and 4.20.5; or

4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; and

4.20.4 Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in RHA 4.20.5, and 4.20.1.1.1 and 4.20.1.1.2, or 4.20.1.2.1 and 4.20.1.2.2, or 4.20.3, or 4.20.3.1 and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

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4.20.5 Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Deleted: 4.20.4 . Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

RHA 4.21 TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST

Except as provided in RHA 4.23, the licensee shall require the authorized medical physicist to be an individual who--

4.21.1 Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraphs 4.21.3 and 4.21.4 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, ww.nrc.gov.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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Deleted: includes all of the training and experience requirements in RHA 4.21.2 and whose certification has been recognized by the NRC or an Agreement State; or

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4.21.1.1 Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

4.21.1.2 Have 2 years of full-time practical training and/or supervised experience in medical physics—

4.21.1.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

4.21.1.2.1 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 4.54 and 4.74; and

4.21.1.3 Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

4.21.2

Deleted: Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution that includes the tasks listed in RHA 4.29, 4.52, 4.64, 4.65, 4.66, 4.67, 4.68, 4.69 and 4.71 as applicable; and

4.21.2 Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

4.21.2.1 Performing sealed source leak tests and inventories;

4.21.2.2 Performing decay corrections;

4.21.2.3 Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4.21.2.4 Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

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4.21.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 4.21.1 or 4.21.2 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 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

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4.21.4 Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

RHA 4.22 TRAINING FOR AN AUTHORIZED NUCLEAR PHARMACIST

Except as provided in RHA 4.23, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who--

4.22.1 Is certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.) To have its certification process recognized, a specialty board shall require all candidates for certification to;

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(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

4.22.2 Has completed 700 hours in a structured educational program consisting of both:

4.22.2.1 200 hours of classroom and laboratory training in the following areas--

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4.22.2.1.1 Radiation physics and instrumentation;

4.22.2.1.2 Radiation protection;

4.22.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.22.2.1.4 Chemistry of radioactive material for medical use; and

4.22.2.1.5 Radiation biology; and

4.23.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on an NRC or Agreement State license or a permit issued by an NRC or Agreement State broad scope licensee or master material license

permit or by a master material license permittee of broad scope before April 29, 2005, need not comply with the training requirements of RHA 4.20, 4.21 or 4.22, respectively.

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4.23.2 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before April 29, 2005, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D-H of this part.

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RHA 4.24 RECENTNESS OF TRAINING

The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

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4.35.2 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15; or

RHA 4.36 TRAINING FOR UPTAKE, DILUTION, AND EXCRETION STUDIES

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.35 to be a physician who--

4.36.1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 4.36.4 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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Deleted: includes all of the requirements in RHA 4.36.3 and whose certification has been recognized by the NRC or an Agreement State; or

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 byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 4.36.2 and 4.36.3 of this section; and

4.3612 Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.36.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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4.36.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 4.36, 4.39 or 4.43 or equivalent NRC requirements, that the individual has satisfactorily completed the requirements in RHA 4.36.1 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.

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4.37.2 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in RHA 4.39 or 4.43 and 4.39.3.2.7, or an individual under the supervision of either as specified in RHA 4.15;

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RHA 4.39 TRAINING FOR IMAGING AND LOCALIZATION STUDIES

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.37 to be a physician who--

4.39.1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 4.39.3 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

Deleted: includes all of the requirements in RHA 4.39.3 and whose certification has been recognized by the NRC or an Agreement State; or

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 byproduct material for imaging and localization studies that includes the topics listed in paragraphs RHA 4.39.3 and 4.39.4 of this section; and

4.39.1.2 Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

4.39.2 Is an authorized user under RHA 4.43 and meets the requirements in RHA 4.39.3.2.7 or equivalent NRC requirements; or

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

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

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4.39.3.2.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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4.39.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 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 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.

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RHA 4.43 TRAINING FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED

Except as provided in RHA 4.23, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RHA 4.40 to be a physician who--

4.43.1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraphs 4.43.2.2.7 and 4.43.3 of this section. (Specialty boards whose certification processes have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.) To be recognized, a specialty board shall require all candidates for certification to:

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Deleted: includes all of the requirements in RHA 4.43.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.43.1.1 Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 4.43.2.1 through 4.43.2.2.5 of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.43.1.2 Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

4.43.2 Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques

applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include--

4.43.2.1 Classroom and laboratory training in the following areas--

4.43.2.1.1 Radiation physics and instrumentation;

4.43.2.1.2 Radiation protection;

4.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.2.1.5 Radiation biology; and

4.43.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

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4.43.2.2.6 Reserved

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

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 must be signed by a preceptor authorized user who meets the requirements in RHA 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.

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4.43.4 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

4.43.4.1 Is an authorized user under RHA 4.43 uses listed in RHA 4.43.2.2.7.3 or 4.43.2.2.7.4 or equivalent NRC or Agreement State requirements; or

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4.43.4.1.1 Is an authorized user under RHA 4.46, 4.74, or equivalent NRC or Agreement State requirements and who meets the requirements in RHA 4.43.4.2 of this section; or

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4.43.4.1.2 Is certified by a medical specialty board whose certification process has been recognized by the NRC an Agreement State under RHA 4.46 or 4.74, and who meets the requirements in RHA 4.43.4.2 of this section.

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4.43.4.2 Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, 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. The training must include—

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4.43.4.2.1 Radiation physics and instrumentation;

4.43.4.2.2 Radiation protection;

4.43.4.2.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.4.2.4 Chemistry of byproduct material for medical use; and

4.43.4.2.5 Radiation biology; and

4.43.4.3 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.43, 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--

4.43.4.3.1 Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

4.43.4.3.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.4.3.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.4.3.4 Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

4.43.4.3.5 Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

4.43.4.3.6 Administering dosages to patients or human research subjects, that include at least 3 cases involving 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 at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

4.43.4.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 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 byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.43 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.

4.44.1 Except as provided in RHA 4.23, 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 1.22 Gigabecquerels (33 millicuries), to be a physician who--

4.44.1.1 Is certified by a medical specialty board whose certification process, includes all of the requirements in paragraphs 4.44.1.3 and 4.44.1.4 of this section and whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 4.44.1.5 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, www.nrc.gov.); or

Deleted: includes all of the requirements in RHA 4.44.1.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.44.1.2 Is an authorized user under RHA 4.43, for uses listed in RHA 4.43.2.2.7.1 or 4.43.2.2.7.2, RHA 4.45, or equivalent NRC requirements; or

Deleted: .1, 4.43.2

[2]Experience with at least 3 cases in RHA 4.43.2.2.7.2 also satisfies the requirement in RHA 4.43.2.2.7.1.

4.44.1.4.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

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4.45.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who--

4.45.1.1 Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 4.45.1.3 and 4.45.1.4 of this section, and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph 4.45.1.5 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page, ww.nrc.gov.); or

Deleted: includes all of the requirements in RHA 4.45.1.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.45.1.4.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

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4.45.1.5 Has obtained written certification 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 must be signed by a preceptor authorized user who meets the requirements in RHA 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.

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4.54.1 Except as provided in RHA 4.23, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RHA 4.46 to be a physician who--

4.54.1.1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph 4.54.1.4 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

Deleted: includes all of the requirements in RHA 4.54.1.2 and whose certification has been recognized by the NRC or an Agreement State; or

4.54.1.1.2 Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.54.1.1.3 Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

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 4.54 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

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4.54.1.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 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.

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4.55.1.4 Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RHA 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

Deleted: certification

4.57.1.1 Is certified by a specialty board whose certification process includes all of the requirements in RHA 4.57.1.2 and 4.57.1.3 and whose certification has been recognized by the NRC or an Agreement State; or

4.57.1.3 Has completed Training in the use of the device for the uses requested.

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RHA 4.74 TRAINING FOR USE OF REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

4.74.1 Except as provided in RHA 4.23, the licensee shall require an authorized user of a sealed source for a use authorized under RHA 4.58 to be a physician who--

4.74.1.1 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraphs 4.74.1.4 and 4.74.1.5 of this section. (The names of board certifications which have been recognized by the NRC or an Agreement State will be posted on the NRC's web page, www.nrc.gov.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

Deleted: includes all of the requirements in RHA 4.74.1.2 and whose certification has been recognized by the NRC or an Agreement State; or

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4.74.1.1.1 Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

4.74.1.1.2 Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

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 4.74 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

Deleted: oncology

4.74.1.4 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA 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 must be signed by a preceptor authorized user who meets the requirements in RHA 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.

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4.74.1.5 Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

SUBPART J-- Reserved
(entire subpart is deleted)

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List of Elements

Thulium..... Tm 69

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