Crosswalk of State Citations to the Code of Federal Regulations Citations

South Carolina Department of Health and Environmental Control

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10 CFR 30.34(g)

B **RHA 2.10. Specific Terms and Conditions of Licenses**

2.10.8 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with RHA 4.38. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 4.38.1 of this chapter at the time of generator elution, in accordance with RHA 4.120 of this chapter.

10 CFR 32.72

B **RHA 2.7. Special Requirements for Issuance of Certain Specific Licenses for Radioactive Materials**

2.7.5.1.4 The applicant ~~satisfies~~ commits to the following labeling requirements:

2.7.5.2.5.1 A copy of each individual's certification by a specialty board whose certification process has been recognized by the ~~Nuclear Regulatory~~ Commission or an Agreement State as specified ~~in Part 4 of this Regulation with the written attestation signed by a preceptor as required by Part 4 of this Regulation~~RHA 4.22.1; or

2.7.5.4 A licensee shall satisfy the labeling requirements in paragraph 2.7.5.1.4 of this section.

2.7.5.45 Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

10 CFR 35.2

B **RHA 4.2. Definitions**

4.2.4 "*Associate Radiation Safety Officer*" means an individual who—

4.2.4.1 Meets the requirements in §§ 35.50 and 35.59; and

4.2.4.2 Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on—

4.2.4.2.1 A specific medical use license issued by the Commission or an Agreement State; or

4.2.4.2.2 A medical use permit issued by a Commission master material licensee.

4.2.45 "Authorized medical physicist" means an individual who--

4.2.45.1 Meets the requirements in RHA 4.21.1 and RHA 4.24; or

4.2.45.2 Is identified as an authorized medical physicist or teletherapy physicist on--

4.2.45.2.1 A specific medical use license issued by the NRC or an Agreement state;

4.2.45.2.2 A medical use permit issued by an NRC master material licensee;

4.2.45.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee; or

4.2.45.2.4 A permit issued by an NRC master material license broad scope medical use permittee.

4.2.56 "Authorized nuclear pharmacist" means a pharmacist who--

4.2.56.1 Meets the requirements in RHA 4.22.1 and RHA 4.24; or

4.2.56.2 Is identified as an authorized nuclear pharmacist on—

4.2.56.2.1 A specific license issued by the NRC or Agreement State that authorizes medical use or the practice of nuclear pharmacy; or

4.2.56.2.2 A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.56.2.3 A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.56.2.4 A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

4.2.56.3 Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4.2.56.4 Is designated as an authorized nuclear pharmacist in accordance with RHA 2.7.5.2.4.

4.2.67 "Authorized user" means a physician, dentist, or podiatrist who--

4.2.67.1 Meets the requirements in RHA 4.24 and RHA 4.36.1, RHA 4.39.1, RHA 4.43.1, RHA 4.44.1.1, RHA 4.45.1.1, RHA 4.54.1.1, RHA 4.57.1.1, or RHA 4.74.1.1; or

4.2.67.2 Is identified as an authorized user on--

4.2.67.2.1 An NRC or Agreement State license that authorizes the medical use of radioactive material;

4.2.~~6~~7.2.2 A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

4.2.~~6~~7.2.3 A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4.2.~~6~~7.2.4 A permit issued by an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

4.2.~~7~~8 "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

4.2.~~8~~9 "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

4.2.~~9~~10 "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with RHA 4.33.

4.2.~~10~~11 "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

4.2.~~11~~12 "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

4.2.~~12~~13 "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

4.2.~~13~~14 "High dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.~~14~~15 "Low dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

4.2.~~15~~16 "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

4.2.~~16~~17 "Manual brachytherapy," as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

4.2.~~17~~18 "Medical event" means an event that meets the criteria in RHA 4.117.1.

4.2.~~18~~19 "Medical institution" means an organization in which more than one medical discipline is practiced.

4.2.~~19~~20 "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

4.2.~~20~~21 "Medium dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

4.2.~~21~~22 "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

D 4.2.23 "*Ophthalmic physicist*" means an individual who—

4.2.23.1 Meets the requirements in §§ 35.433(a)(2) and 35.59; and

4.2.23.2 Is identified as an ophthalmic physicist on a—

4.2.23.2.1 Specific medical use license issued by the Commission or an Agreement State;

4.2.23.2.2 Permit issued by a Commission or Agreement State broad scope medical use licensee;

4.2.23.2.3 Medical use permit issued by a Commission master material licensee; or

4.2.23.2.4 Permit issued by a Commission master material licensee broad scope medical use permittee.

4.2.~~22~~24 "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for specified set of exposure conditions.

4.2.~~23~~25 "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

4.2.~~24~~26 "Pharmacist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

4.2.~~25~~27 "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

4.2.~~26~~28 "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4.2.~~27~~29 "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

4.2.~~28~~30 "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 or an Associate Radiation Safety Officer.

4.2.~~29~~31 "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented--

4.2.~~29~~31.1 In a written directive; or

4.2.~~29~~31.2 In accordance with the directions of the authorized user for procedures performed pursuant to RHA 4.35 and 4.37.

4.2.~~30~~32 "Prescribed dose" means--

4.2.~~30~~32.1 For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

4.2.~~30~~32.2 For teletherapy, the total dose and dose per fraction as documented in the written directive;

4.2.~~30~~32.3 For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4.2.~~30~~32.4 For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

4.2.~~31~~33 "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but—

4.2.~~31~~33.1 Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

4.2.~~31~~33.2 Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

4.2.~~32~~34 "Radiation Safety Officer" means an individual who--

4.2.~~32~~34.1 Meets the requirements in RHA 4.20.1 or 4.20.3 and RHA 4.24; or

4.2.~~32~~34.2 Is identified as a Radiation Safety Officer on--

4.2.~~32~~34.2.1 A specific medical use license issued by the NRC or Agreement State; or

4.2.~~32~~34.2.2 A medical use permit issued by an NRC master material licensee.

4.2.~~33~~35 "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

4.2.~~34~~36 "Sealed Source and Device Registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

4.2.~~35~~37 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

4.2.~~36~~38 "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

4.2.~~37~~39 "Teletherapy," as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

4.2.~~38~~40 "Temporary job" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

4.2.~~39~~41 "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

4.2.~~40~~42 "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

4.2.~~41~~43 "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

4.2.~~42~~44 "Type of use" means use of radioactive material under RHA 4.35, 4.37, 4.40, 4.46, 4.56 4.58 or 4.88.

4.2.~~43~~45 "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

4.2.~~44~~46 "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RHA 4.17.

10 CFR 35.12

D **RHA 4.7. Application for License, Amendment, or Renewal**

4.7.2.1 Filing an original of DHEC Form 0813, "Application for Radioactive Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

4.7.3.1.2 A letter ~~requesting the amendment or renewal~~containing all information required by DHEC Form 0813; and

4.7.4 In addition to the requirements in RHA 4.7.2 and 4.7.3 of this section an application for a license or amendment for medical use of radioactive material as described in RHA 4.88 must also include: ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.~~

4.7.4.1 ~~The applicant shall also provide specific information on:~~Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;

4.7.4.~~1.1~~2 ~~Radiation safety precautions and instructions~~Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific RHA 4.88 medical use;

4.7.4.~~1.2~~3 ~~Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and~~Any Additional specific information on--

4.7.4.~~1.~~3.1 ~~Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.~~Radiation safety precautions and instructions;

4.7.4.3.2 Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4.7.4.3.3 Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

4.7.4.~~2~~4 ~~The applicant or licensee shall also provide~~ ~~a~~Any other information requested by the Department in its review of the application.

10 CFR 35.13

D **RHA 4.8 License amendments**

4.8.2 Before it permits anyone to work as an authorized user, ~~authorized nuclear pharmacist, or~~ authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except--

4.8.2.1 For an authorized user, an individual who meets the requirements in RHA 4.24, RHA 4.36.1, 4.39.1, 4.43.1, 4.44.1.1, 4.45.1.1, 4.54.1.1, 4.57.1.1, 4.74.1.1~~, 4.76, 4.77, 4.78, 4.79, 4.80, 4.81, 4.82, 4.83 or 4.84 and RHA 4.24~~;

4.8.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in RHA 4.22.1 ~~or 4.86~~ and RHA 4.24;

4.8.2.3 For an authorized medical physicist, an individual who meets the requirements in RHA 4.21.1 ~~or 4.85~~ and RHA 4.24;

4.8.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or an ophthalmic physicist—

4.8.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

4.8.~~4~~5 Before it receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

4.8.~~5~~6 Before it adds to or changes the areas of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either RHA 4.35 or 4.37;

4.8.~~6~~7 Before it changes the address(es) of use identified in the application or on the license; ~~and~~

4.8.~~7~~8 Before it revises procedures required by RHA 4.61, 4.67, 4.68 and 4.69, as applicable, where such revision reduces radiation safety~~.~~; and

4.8.9 Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

10 CFR 35.14

~~RHA 4.9. Notifications~~

~~4.9.1 A licensee shall provide the Department a copy of the board certification, the NRC or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under RHA 4.8.2.1 through 4.8.2.4.~~

~~4.9.2 A licensee shall notify the Department by letter no later than 30 days after:~~

~~4.9.2.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;~~

~~4.9.2.2 The licensee's mailing address changes;~~

~~4.9.2.3 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.15; or~~

~~4.9.2.4 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or 4.37.~~

~~4.9.3 The licensee shall mail the documents required in this section to the appropriate address identified in RHA 1.13.~~

D RHA 4.9 Notifications

4.9.1 A licensee shall provide the Department, no later than 30 days after the date that the licensee permits an individual to work under the provisions of RHA 4.8.2 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist—

4.9.1.1 A copy of the board certification and, as appropriate, verification of completion of:

4.9.1.1.1 Training for the authorized medical physicist under RHA 2.21.4;

4.9.1.1.2 Any additional case experience required in RHA 4.43.2.2.7 for an authorized user under RHA 4.40; or

4.9.1.1.3 Device specific training in RHA 4.74.1.5 for the authorized user under RHA 4.58; or

4.9.2 A copy of the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

4.9.2.1 A licensee shall notify the Department no later than 30 days after:

4.9.2.1.1 An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

4.9.2.1.2 The licensee permits an individual qualified to be a Radiation Safety Officer under RHA 4.20 and 4.24 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with RHA 4.13.3;

4.9.2.1.3 The licensee's mailing address changes;

4.9.2.1.4 The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RHA 2.10.2.1 of this chapter;

4.9.2.1.5 The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either RHA 4.35 or RHA 4.37 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

4.9.2.1.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RHA 4.8.9. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

4.9.3 The licensee shall send the documents required in this section to the appropriate address identified in RHA 1.13.

10 CFR 35.15

D **RHA 4.10. Exemptions Regarding "Type A" Specific Licenses of Broad Scope**

4.10.3 The provisions of RHA 4.8.~~5~~6 regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

D 4.10.5 The provisions of RHA 4.9.2.1.1 for an authorized user, an authorized nuclear pharmacist, ~~or an~~, authorized medical physicist or an ophthalmic physicist;

10 CFR 35.15

H&S **RHA 4.13. Authority and Responsibilities for the Radiation Protection Program**

4.13.2 A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

D 4.13.3 For up to 60 days each year, a licensee may permit ~~an authorized user or~~ an individual qualified to be a Radiation Safety Officer, under RHA 4.20 and 4.24, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in RHA 4.13.7 of this section, if the licensee takes the actions required in RHA 4.13.2, 4.13.3, 4.13.7 and 4.13.8 of this section and notifies the Department in accordance with RHA 4.9.2.

10 CFR 35.40

H&S **RHA 4.17. Written Directives**

4.17.2.5 For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

4.17.2.6 For permanent implant brachytherapy:

4.17.2.6.1 Before implantation: The treatment site, the radionuclide, and the total source strength; and

4.17.2.6.2 After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

4.17.2.~~6~~7 For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

4.17.2.~~6~~7.1 Before implantation: the treatment site, ~~the~~ radionuclide, and dose; and

4.17.2.~~6~~7.2 After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose)~~.~~; and date.

10 CFR 35.41

H&S **RHA 4.18. Procedures for Administrations Requiring a Written Directive**

4.18.2.3 Checking both manual and computer-generated dose calculations; ~~and~~

4.18.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RHA 4.58 or RHA 4.88.

4.18.2.5 Determining if a medical event, as defined in RHA 4.117, has occurred; and

4.18.2.6 Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

10 CFR 35.50

B **RHA 4.20. Training for Radiation Safety Officers and Associate Radiation Safety Officer**

Except as provided in RHA 4.23, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RHA 4.13 to be an individual who--

4.20.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Commission 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.)~~ The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.

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

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

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~~Commission 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 4.23, 4.39 or RHA 4.43; and

4.20.2.2 One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Office on ~~NRC~~Commission or Agreement State license or on a permit issued by an ~~NRC~~Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following— ~~involving the following –~~

4.20.2.3 This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs RHA 4.20.2 and RHA 4.20.4 of this section, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

~~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 radioactive 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~~

4.20.3 Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under RHA 4.21.1, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.1 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph 4.20.4 of this section; or

4.20.3.2 Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in paragraph 4.20.4 of this section.

~~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~~

4.20.~~5~~4 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, an Associate 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

10 CFR 35.51

B **RHA 4.21. Training for an Authorized Medical Physicist**

4.21.1 Is certified by a specialty board whose certification process has been recognized by the ~~NRC~~Commission or an Agreement State and who meets the requirements in paragraph~~s 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, www.nrc.gov.)~~ The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.21.1.2.1 Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or

~~4.21.3~~4.21.2.5 Has obtained written attestation that the individual has satisfactorily completed the requirements in RHA ~~4.21.4 and 4.21.1.1 and 4.21.1.2 or~~ 4.21.2 and 4.21.~~4~~3 of this section, and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties 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 4.23, or equivalent ~~NRC~~Commission 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~~.

4.21.~~4~~3 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.

10 CFR 35.55

B **RHA 4.22. Training for an Authorized Nuclear Pharmacist**

4.22.1 Is certified ~~as a nuclear pharmacist~~ by a specialty board whose certification process has been recognized by the ~~NRC~~Commission or an Agreement ~~State and who meets the requirements in paragraph 4.22.3 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, www.nrc.gov.)~~ names of board certifications have been recognized by the Commission or Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.22.3 Has obtained written attestation signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in RHA 4.22.2 of this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

10 CFR 35.57

B&D **RHA 4.23. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist**

~~4.23.1 An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized 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.~~

~~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 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 DH of this part.~~

~~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.~~

4.23.1.1 An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of RHA 4.20, RHA 4.21, or RHA 4.22, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RHA 4.20.4 or RHA 4.21.3, as appropriate, for any material or uses for which they were not authorized prior to this date.

4.23.1.2 Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American

Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RHA 4.20 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.3 Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, xray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RHA 4.21, for those materials and uses that these individuals performed on or before October 24, 2005.

4.23.1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of RHA 4.20, RHA 4.21 or RHA 4.22, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

4.23.2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.

4.23.2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

4.23.2.2.1 For uses authorized under RHA 4.35 or RHA 4.37, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

4.23.2.2.2 For uses authorized under RHA 4.40, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

4.23.2.2.3 For uses authorized under RHA 4.46 or RHA 4.58, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

4.23.2.2.4 For uses authorized under RHA 4.56, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

4.23.2.3 Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

4.23.3.1 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 licenses for the same uses for which these individuals are authorized.

10 CFR 35.65

D **RHA 4.28. Authorization for Calibration, Transmission, and Reference Sources**

4.28.1 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent NRC or Agreement State regulations.

4.28.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RHA 2.7.7 of this chapter or equivalent NRC or Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

4.28.3 Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4.28.4 Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 uCi) or 1000 times the quantities in Appendix C, RHA 3.54, of Part III of these regulations.

4.28.5 Technetium-99m in amounts as needed.

4.28.6 Radioactive material in sealed sources authorized by this provision shall not be:

4.28.6.1 Used for medical use as defined in RHA 4.2 except in accordance with the requirements in RHA 4.56 or

4.28.6.2 Combined (*i.e.,* bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

4.28.6.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in this section need not list these sources on a specific medical use license.

Change:

RHA 4.35. Use of Unsealed ~~Byproduct~~Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is not Required

10 CFR 35.190

B **RHA 4.36. Training for Uptake, Dilution, and Excretion Studies**

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

4.36.3.3 ~~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 4.36.1.1 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.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.36.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 4.35. The attestation must be obtained from either:

4.36.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43, or equivalent Agreement State requirements; or

4.36.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.36, 4.39 or 4.43, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency

program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.36.3 of this section.

~~4.36.4 Has obtained written certification, 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 4.36.3 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RHA 4.35~~

10 CFR 35.204

H&S **RHA 4.38. Permissible Molybdenum-99, ~~Concentration~~ Strontium-82, and Strontium-85 Concentrations.**

4.38.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration ~~of the first eluate after receipt of a~~in each eluate from a generator to demonstrate compliance with RHA 4.38.1.

4.38.3 A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with RHA 4.38.1.

4.38.~~3~~4 If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with RHA 4.101.

4.38.5 The licensee shall report any measurement that exceeds the limits in RHA 4.38.1 of this section at the time of generator elution, in accordance with RHA 4.120.

10 CFR 35.290

B **RHA 4.39. Training for Imaging and Localization Studies**

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

4.39.3.2 Work experience, under the supervision of an authorized user~~,~~ who meets the requirements in RHA 4.23, 4.39 or 4.43 and 4.39.3.2.7 or equivalent NRC or Agreement State requirements~~,~~. An authorized nuclear pharmacist who meets the requirements in RHA 4.22 or RHA 4.23 may provide the supervised work experience for paragraph 4.39.3.2.7 of this section. Work experience must involve— ~~involving~~ –

4.39.3.3 ~~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.~~ Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.39.3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.35. and 4.37. The attestation must be obtained from either:

4.39.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7, or equivalent NRC or Agreement State requirements; or

4.39.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.39, or RHA 4.43 and RHA 4.39.3.2.7 or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.39.3 of this section.

Change:

SUBPART E. UNSEALED ~~BYPRODUCT~~RADIOACTIVE MATERIAL...WRITTEN DIRECTIVE REQUIRED

10 CFR 35.300

B **RHA 4.40. Use of Unsealed ~~Byproduct~~Radioactive Material for Which a Written Directive is Required**

A licensee may use any unsealed ~~byproduct~~radioactive material identified in RHA 4.43.4.3.6 prepared for medical use and for which a written directive is required that is--

10 CFR 35.390

B **RHA 4.43. Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required**

4.43.1 Is certified by a medical specialty board whose certification process has been recognized by the ~~NRC~~Commission 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~~The names of board certifications that have been recognized by the ~~NRC~~Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov~~Medical Uses Licensee Toolkit Web page.~~)~~ To be recognized, a specialty board shall require all candidates for certification to:

4.43.2.2.7 ~~Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is~~

~~requesting authorized user status --~~Administering dosages of radioactive drugs to patients or research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RHA 4.88. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

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

4.43.2.2.7.2 Oral administration of greater than 1.22 ~~G~~gigabecquerels (33 millicuries) of sodium iodide I-131; ~~2~~[2]

4.43.2.2.7.3 ~~Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or~~Parenteral administration of radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less that 150 keV, for which a written directive is required; and

~~4.43.2.2.7.4 Parenteral administration of any other radionuclide, for which a written directive is required; and~~

~~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 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) as the individual requesting authorized user status.~~

4.43.2.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 4.43.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RHA 4.40 for which the individual is requesting authorized user status. The attestation must be obtained from either:

4.43.2.3.1 A preceptor authorized user who meets the requirements in 4.23, 4.40, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

4.43.2.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 4.23, 4.40, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph 4.43.2 of this section.

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

10 CFR 35.396

4.43.43 Training for the parenteral administration of unsealed radioactive material requiring a written directive.

4.43.3.1 Except as provided in RHA 4.23, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—

4.43.43.1.1 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

4.43.43.1.~~1~~2 Is an authorized user under RHA 4.~~46~~54, 4.74, or equivalent NRC or Agreement State requirements and who meets the requirements in RHA 4.43.43.2 of this section; or

4.43.43.1.~~2~~3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under RHA 4.~~46~~54 or 4.74, and who meets the requirements in RHA 4.43.43.2 of this section.

4.43.3.2 The Physician--

4.43.43.2.1 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 photonemitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~ listed in RHA 4.43.2.2.7.3. The training must include--

4.43.43.2.1.1 Radiation physics and instrumentation;

4.43.43.2.1.2 Radiation protection;

4.43.43.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;

4.43.43.2.1.4 Chemistry of radioactive material for medical use; and

4.43.43.2.1.5 Radiation biology; and

4.43.4.3.2.2 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 4.43.43 or equivalent NRC or Agreement State requirements, in the 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~~ listed RHA 4.43.2.2.7.3. A supervising authorized user who meets the requirements in RHA 4.43, 4.43.3, or equivalent NRC or Agreement State requirements 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~~in the same category or categories as the individual requesting authorized user status. The work experience must involve--

4.43.~~4.~~3.~~1~~2.2.1 Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

4.43.~~4.~~3.2.2.2 Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

4.43.~~4.~~3.~~3~~2.2.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.43.~~4.~~3.~~4~~2.2.4 Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

4.43.~~4.~~3.~~5~~2.2.5 Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

4.43.~~4.~~3.2.2.6 Administering dosages to patients or human research subjects, that include at least ~~3~~three 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~~ of parenteral administrations as specified in RHA 4.43.2.2.7.3; and

~~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.~~

4.43.3.3 Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

4.43.3.3.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent NRC or Agreement State requirements. A preceptor authorized user who meets the requirements in RHA 4.43, RHA 4.43.3, or equivalent NRC or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

4.43.3.3.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.43.3, or equivalent NRC or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.43.3.2.1 and 4.43.3.2.2 of this section.

10 CFR 35.392

B **RHA 4.44. Training 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)**

~~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~~Commission or an Agreement State. ~~and who meets the requirements in paragraph 4.44.1.5 of this section. (~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov~~Medical Uses Licensee Toolkit Web page.~~)~~; 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

4.44.~~1.~~3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include-

4.44.~~1.~~3.1 Radiation physics and instrumentation;

4.44.~~1.~~3.2 Radiation protection;

4.44.~~1.~~3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.44.~~1.~~3.4 Chemistry of radioactive material for medical use; and

4.44.~~1.~~3.5 Radiation biology; and

4.44.~~1.4~~3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 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—

4.44.~~1.4.1~~3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.44.~~1.4.2~~3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.44.~~1.4.3~~3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.44.~~1.4.4~~3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.44.~~1.4.5~~3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.44.~~1.4.6~~3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

4.44.~~1.5~~3.7 ~~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 attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 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.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.44.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

4.44.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent NRC or bAgreement State requirements and has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2; or

4.44.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.43, RHA 4.44, RHA 4.45, or equivalent Agreement State requirements, has experience in administering dosages as specified in RHA 4.43.2.2.7.1 or RHA 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.44.1.3 and 4.44.1.4 of this section.

10 CFR 35.394

B **RHA 4.45. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)**

~~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~~Commission or an Agreement State~~,~~. ~~and who meets the requirements in paragraph 4.45.1.5 of this section.~~ ~~(~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Commission or an Agreement State ~~will be~~are posted on the NRC's ~~Web page, www.nrc.gov~~Medical Uses Licensee Toolkit Web page.~~)~~; or

4.45~~.1~~.2 Is an authorized user under RHA 4.43.1, 4.43.2 for uses listed in RHA 4.43.2.2.7.2, or equivalent NRC requirements; or

4.45~~.1~~.3 Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include-

4.45~~.1~~.3.1 Radiation physics and instrumentation;

4.45~~.1~~.3.2 Radiation protection;

4.45~~.1~~.3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.45~~.1~~.3.4 Chemistry of radioactive material for medical use; and

4.45~~.1~~.3.5 Radiation biology; and

4.45.~~1.4~~3.6 Has work experience, under the supervision of an authorized user who meets the requirements in RHA 4.23, 4.43, 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--

4.45.~~1.4.1~~3.6.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

4.45.~~1.4.2~~3.6.2 Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

4.45.~~1.4.3~~3.6.3 Calculating, measuring, and safely preparing patient or human research subject dosages;

4.45.~~1.4.4~~3.6.4 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.45.~~1.4.5~~3.6.5 Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

4.45.~~1.4.6~~3.6.6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I131; and

4.45.~~1.5~~3.7 ~~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 attestation must be signed by a preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 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.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.45.3 of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under RHA 4.40. The attestation must be obtained from either:

4.45.3.7.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.43, 4.45 or equivalent NRC or Agreement State requirements and has experience in administering dosages as specified in 4.43.2.2.7.2; or

4.45.3.7.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.43, 4.45, or equivalent Agreement State requirements, has experience in administering dosages as specified in 4.43.2.2.7.2, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.45.3 of this section.

10 CFR 35.400

C **RHA 4.46. Use of Sources for Manual Brachytherapy**

4.46.1 A licensee ~~shall~~must use only brachytherapy sources ~~for therapeutic medical uses~~:

4.46.1.1 ~~As approved in the Sealed Source and Device Registry~~Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.46.1.2 ~~In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of~~In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

10 CFR 35.433

B H&S **RHA 4.52. ~~Decay of Strontium-90 Sources for Ophthalmic Treatments~~ Strontium-90 sources for ophthalmic treatments.**

~~4.52.1 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51.~~

~~4.52.2 A licensee shall retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.~~

4.52.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in 4.52.2 of this section are performed by either:

4..52.1.1 An authorized medical physicist; or

4.52.1.2 An individual who:

4.52.1.2.1 is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and

4.52.1.2.2 holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

4.52.1.2.3 has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4.52.1.2.4 Has documented training in:

4.52.1.2.4.1 The creation, modification, and completion of written directives;

4.52.1.2.4.2 Procedures for administrations requiring a written directive; and

4.52.1.2.4.3 Performing the calibration measurements of brachytherapy sources as detailed in RHA 4.51.

4.52.2 The individuals who are identified in 4.52.1 of this section must:

4.52.2.1 Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RHA 4.51; and

4.52.2.2 Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 4.52.1 of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

4.52.3 Licensees must retain a record of the activity of each strontium-90 source in accordance with RHA 4.106.

10 CFR 35.490

B **RHA 4.54. Training for Use of Manual Brachytherapy Sources**

~~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 NRCCommission or an Agreement State,. and who meets the requirements in paragraph 4.54.1.4 of this section. (The names of board certifications whichthat have been recognized by the NRCCommission or an Agreement State will beare posted on the NRC's Web pageMedical Uses Licensee Toolkit web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.54.1.1.1 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

4.54.1.1.2 Pass an examination, administered by diplomats 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

4.54.1.22 Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes--

4.54.1.2.1 200 hours of classroom and laboratory training in the following areas:

4.54.1.2.1.1 Radiation physics and instrumentation;

4.54.1.2.1.2 Radiation protection;

4.54.1.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.54.1.2.1.4 Radiation biology; and

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 or Agreement State requirements at a medical institutionfacility authorized to use radioactive material under RHA 4.4.6, involving—

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

4.54.1.2.2.2 Checking survey meters for proper operation;

4.54.1.2.2.3 Preparing, implanting, and removing brachytherapy sources;

4.54.1.2.2.4 Maintaining running inventories of material on hand;

4.54.1.2.2.5 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.54.1.2.2.6 Using emergency procedures to control radioactive material; and

4.54.1.32.3 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

4.54.~~1.~~42.4 ~~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.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.54.2.1 and 4.54.2.2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RHA 4.46. The attestation must be obtained from either:

4.54.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent NRC or Agreement State requirements; or

4.54.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, RHA 4.54, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.54.2.1 and 4.54.2.2 of this section.

10 CFR 35.491

B **RHA 4.55. Training for Ophthalmic Use of Strontium-90**

~~4.55.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who--

4.55.~~1.~~1 Is an authorized user under RHA 4.54 or equivalent NRC requirements; or

4.55.~~1.~~2 Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include--

4.55.~~1.~~2.1 Radiation physics and instrumentation;

4.55.~~1.~~2.2 Radiation protection;

4.55.~~1.~~2.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.55.~~1.~~2.4 Radiation biology; and

4.55.~~1.~~3 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

4.55.~~1.~~3.1 Examination of each individual to be treated;

4.55.~~1.~~3.2 Calculation of the dose to be administered;

4.55.~~1.~~3.3 Administration of the dose; and

4.55.~~1.~~3.4 Follow up and review of each individual's case history; and

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~~paragraphs 4.55.2 and 4.55.3of this section and ~~has achieved a level of competency sufficient to function independently~~is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

10 CFR 35.500

C **RHA 4.56. Use of Sealed Sources and Medical Devices for Diagnosis**

~~A licensee shall use only sealed sources for diagnostic medical uses as approved in the NRC Sealed Source and Device Registry.~~

4.56.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

4.56.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

10 CFR 35.590

B **RHA 4.57. Training for Use of Sealed Sources and Medical Devices for Diagnosis**

~~4.57.1~~ Except as provided in RHA 4.23, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under RHA 4.56 to be a physician, dentist, or podiatrist who--

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

4.57.1.1 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 of this section and whose certification has been recognized by the ~~NRC~~Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

4.57.2 Is an authorized user for uses listed in RHA 4.37 or equivalent NRC or Agreement State requirements; or

4.57.~~1.2~~3 Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include--

4.57.~~1.2~~3.1 Radiation physics and instrumentation;

4.57.~~1.2~~3.2 Radiation protection;

4.57.~~1.2~~3.3 Mathematics pertaining to the use and measurement of radioactivity;

4.57.~~1.2~~3.4 Radiation biology; and

4.57.~~1.3~~4 Has completed training in the use of the device for the uses requested.

10 CFR 35.600

C **RHA 4.58. Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit**

~~4.58.1 A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

~~4.58.1.1 As approved in the NRC Sealed Source and Device Registry; or~~

~~4.58.1.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.~~

4.58.1 A licensee must only use sealed sources:

4.58.1.1 Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

4.58.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RHA 4.19.1 are met.

4.58.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

4.58.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

4.58.2.2 In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RHA 4.19.1 are met.

10 CFR 35.610

H&S **RHA 4.61. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**

~~4.61.4 A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in –~~

~~4.61.4.1 The procedures identified in RHA 4.61.1.4; and~~

~~4.61.4.2 The operating procedures for the unit.~~

4.61.4.1 Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

4.61.4.2 A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—

4.61.4.2.1 The procedures identified in paragraph 4.61.1.4 of this section; and

4.6.1.4.2.2 The operating procedures for the unit.

4.61.7 A licensee shall retain a copy of the procedures required by RHA 4.61.1.4 and 4.61.1.2 of this section in accordance with RHA 4.108.

10 CFR 35.655(a)

H&S **RHA 4.72. ~~Five-Year Inspection~~Full-inspection servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units**

4.72.1 ~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism

and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

4.72.3 A licensee shall keep a record of the inspection and servicing in accordance with RHA 4.116.

10 CFR 35.690

B **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~~Commission or an Agreement State and who meets the requirements in paragraph~~s 4.74.1.4 and 4.74.1.5~~4.74.3 of this section. ~~(~~The names of board certifications ~~which~~that have been recognized by the ~~NRC~~Commission or an Agreement State ~~will be~~are posted on the NRC's Medical Uses Licensee Toolkit Web page~~, www.nrc.gov.)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

4.74.1.1~~.1~~ Successfully complete a minimum of 3 years of residency training in radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physician 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 diplomats 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.~~2 Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--

4.74.~~1.~~2.1 200 hours of classroom and laboratory training in the following areas—

4.74.~~1.~~2.1.1 Radiation physics and instrumentation;

4.74.~~1.~~2.1.2 Radiation protection;

4.74.~~1.~~2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

4.74.~~1.~~2.1.4 Radiation biology; and

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~~facility that is authorized to use radioactive materials in RHA 4.58, involving--

4.74.~~1.~~2.2.1 Reviewing full calibration measurements and periodic spot-checks;

4.74.~~1.~~2.2.2 Preparing treatment plans and calculating treatment doses and times;

4.74.~~1.~~2.2.3 Using administrative controls to prevent a medical event involving the use of radioactive material;

4.74.~~1.~~2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

4.74.~~1.~~2.2.5 Checking and using survey meters; and

4.74.~~1.~~2.2.6 Selecting the proper dose and how it is to be administered; and

4.74.~~1~~2.3 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

4.74.~~1~~2.4 ~~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 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.~~Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 4.74.2.1, 4.74.2.2, 4.74.2.3 and 4.74.3 of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

4..74.2.4.1 A preceptor authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

4.74.2.4.2 A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RHA 4.23, 4.74, or equivalent NRC or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs 4.74.2.1, 4.74.2.2, 4.74.2.3 of this section.

4.74.~~1.5~~3 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.

10 CFR 35.2024

D **RHA 4.89. Records of Authority and Responsibilities for Radiation Protection Programs**

4.89.3 For each Associate Radiation Safety Officer appointed under RHA 4.13.2, the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

10 CFR 35.2310

D **RHA 4.102. Records of Safety Instruction**

A licensee shall maintain a record of safety instructions required by RHA 4.41, 4.49 and the operational and safety instructions required by RHA 4.61 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

10 CFR 35.2655

D **RHA 4.116. Records of ~~5-Year Inspection~~Full-inspection servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units**

4.116.1 A licensee shall maintain a record of the ~~5-year inspections~~full-inspection and servicing for teletherapy and gamma stereotactic radiosurgery units required by RHA 4.72 for the duration of use of the unit.

10 CFR 35.3045

C **RHA 4.117. Report and Notification of a Medical Event**

4.117.1 A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which

4.117.1.1 ŧThe administration of radioactive material or radiation from radioactive material, except permament implant brachytherapy, results in—

4.117.1.1.1 A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

4.117.1.1.1.1 The total dose delivered differs from the prescribed dose by 20 percent or more; or

__4.117.1.1.1.2 The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

__4.117.1.1.1.3 The fractionated dose delivered differs from the prescribed dose~~,~~ for a single fraction, by 50 percent or more.

__4.117.1.1.2 A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

_____4.117.1.1.2.1 An administration of a wrong radioactive drug containing radioactive material; or

_____4.117.1.1.2.2 An administration of a radioactive drug containing radioactive material by the wrong route of administration; or

_____4.117.1.1.2.3 An administration of a dose or dosage to the wrong individual or human research subject; or

_____4.117.1.1.2.4 An administration of a dose or dosage delivered by the wrong mode of treatment; or

_____4.117.1.1.2.5 A leaking sealed source.

~~4.117.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~

4.117.1.1.3 A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

__4.117.1.1.3.1 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

__4.117.1.1.3.2 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4.117.1.2 For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

__4.117.1.2.1 The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

__4.117.1.2.2 The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

4.117.1.2.3 An administration that includes any of the following:

4.117.1.2.3.1 The wrong radionuclide;

4.117.1.2.3.2 The wrong individual or human research subject;

4.117.1.2.3.3 Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4.117.1.2.3.4 A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

10 CFR 35.3204

C **RHA 4.120 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations**

4.120.1 The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 4.38.1 at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

4.120.2 By an appropriate method listed in RHA 1.13 of this chapter, the licensee shall submit a written report to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 4.120.1 of this section.

RATS ID: 2018-2

D 10 CFR 37.7(a) is addressed in RHA 1.13
B&C 10 CFR 37.77 does appear in SC Regs (these notifications should be made to State)
C 10 CFR 37.81(g) is already in regs 12.25 (the same as NRC)
D 10 CFR 70.5 (SC does not have Regs dealing with Safeguards)
B 10 CFR 71.97 covered in RHA 2.22 (adopt 10 CFR 71 by reference)

RATS ID : 2018-3

C 10 CFR 34.101(c) Is covered under reciprocity in RHA 2

10 CFR 37.23(b)(2)

B **RHA 12.5 Access authorization program requirements**

12.5.2.2 Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Licensees shall provide oath or affirmation certificates to the Department. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with RHA 12.6.3.

10 CFR 37.43(b)(2)

C **RHA 12.12 General security program requirements**

12.12.4.2 Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan ~~and~~, implementing procedures and the list of individuals that have been approved for unescorted access.

12.12.4.3 Before granting an individual access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

12.12.4.3.1 Evaluate an individual's need to know the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access; and

12.12.4.5 The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.6 Licensees shall maintain a list of persons currently approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

12.12.4.7 When not in use, the licensee shall store its security plan ~~and~~, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

12.12.4.8.2 The list of individuals approved for access to the security plan ~~or~~, implementing procedures, or the list of individuals that have been approved for unescorted access.

10 CFR 37.45(b) is covered in RHA 12.13.2

10 CFR 37.77(a)(1)

B **RHA 12.23 Advance notification of shipment of Category 1 quantities of radioactive material.**

12.23.1.1 The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone numbers and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, ~~Division of Material Safety, State, Tribal, and Rulemaking Programs,~~ Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to Department may be made by email to RAMQC_shipments@dhec.sc.gov or by fax to 803898-0391. Notifications to the Department must be to the Director, Division of Land & Waste Management, Bureau of Waste Management, 2600 Bull Street, Columbia, SC 29201.

10 CFR 71.97(c)(3)

B 10 CFR 71.97(c)(3) is incorporated in RHA 2.22 by reference

RATS ID: 2019-1

B 10 CFR 37.23(b)(2) is already being changed in RATS ID: 2018-3 RHA 12.5.2.2

10 CFR 37.27(c)(1) and (2)

RHA 12.7 Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material

B 12.7.3.1 For the purpose of complying with this ~~S~~subpart ~~B~~, Department licensees shall use an appropriate method listed in 10 CFR 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director Division of ~~Facilities and Security U.S NRC~~Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-8B20, Rockville, MD 20852~~-2738 ATTN: Criminal History Program, Mail Stop TWB-05 B32M~~, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to~~emailing ~~FORMS~~MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/esubmittals.html~~https://www.nrc.gov/seurity/chp.html.

12.7.3.2 Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to ''U.S. NRC.'' (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301–415–7513~~Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals~~Licensee Crimnial History Records Check & Firearms Background Check information page at ~~http://www.nrc.gov/site-help/e-submittals.html~~https://www.nrc.gov/security/chp/html and see the link for ~~the Criminal History Program under Electronic Submission Systems~~How do I determine how much to pay for the request?).

RATS ID: 2019-2

B 10 CFR 71.17(c)(3) is addressed in RHA 1.13 "Communications"

C 10 CFR 71.101 Quality Assurance requirements (this is being adopted in the 2020 reg revision)

RATS ID: 2020-1

10 CFR 34.47

C **RHA 5.14. Personnel Monitoring Control**

5.14.1 The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming rate meter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

5.14.4 If an individual's pocket chamber is found to be off scale, or if his or her electronic personal dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in records to be maintained by the licensee until the Department terminates the license.

5.14.7.3 Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Department terminates the license.

10 CFR 34.83

C **Records of Personnel Monitoring**

5.14.7.3 Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Department terminates the license.

10 CFR 36.55

H&S **RHA 11.20. Personnel Monitoring**

11.20.1 Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be ~~accredited by the National Voluntary Laboratory Accreditation Program for~~capable of detecting high energy photons in the normal and accident dose ranges ~~(see RHA 3.16.3)~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

10 CFR 39.65

C RHA 8.21. Personnel Monitoring

8.21.1 The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears~~,~~a personnel dosimeter at all times during the handling of radioactive materials~~, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter must be promptly processed~~All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

RATS ID: 2020-2

10 CFR 35.3045(g)(1)(ii)

C **RHA 4.117. Report and Notification of a Medical Event**

4.117.7.1.2 ~~Social security number or other identification number, if one has been assigned,~~Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

10 CFR 35.3047(f)(1)(ii)

C **RHA 4.118. Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child**

4.118.6.1.2 ~~Social security number or other identification number, if one has been assigned,~~ Identification number or if no other identification number is available, the social security number of the ~~pregnant individual or the nursing child~~individual who is the subject of the event; and