PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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Subpart A--General Information

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§ 35.1 Purpose and scope.

This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 37, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

[78 FR 17007, Mar. 19, 2013]

§ 35.2 Definitions.

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Address of use means the building or buildings that are identified on the license and where byproduct material may be received, prepared, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

Associate Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50 and 35.59; and

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

(i) A specific medical use license issued by the Commission or an Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Authorized medical physicist means an individual who—

Meets the requirements in §§ 35.51(a) and 35.59; or

(2) Is identified as an authorized medical physicist or teletherapy physicist on—

(i) A specific medical use license issued by the Commission or Agreement State;

(ii) A medical use permit issued by a Commission master material licensee;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee.

Authorized nuclear pharmacist means a pharmacist who—

(1) Meets the requirements in §§ 35.55(a) and 35.59; or

(2) Is identified as an authorized nuclear pharmacist on—

(i) A specific license issued by the Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

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

(4) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

Authorized user means a physician, dentist, or podiatrist who—

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or

(2) Is identified as an authorized user on—

(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;

(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;

(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or

(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

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.

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.

Client's address means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with § 35.80.

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

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.

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.

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.

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.

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.

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.

Medical event means an event that meets the criteria in § 35.3045(a) or (b).

Medical institution means an organization in which more than one medical discipline is practiced.

Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.

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) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Mobile medical service means the transportation of byproduct material to and its medical use at the client's address.

Ophthalmic physicist means an individual who—

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

(2) Is identified as an ophthalmic physicist on a—

(i) Specific medical use license issued by the Commission or an Agreement State;

(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a Commission master material licensee; or

(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.

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 a specified set of exposure conditions.

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.

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.

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.

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.

Positron Emission Tomography (PET) radionuclide production facility is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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

Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented—

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.

Prescribed dose means—

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

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—

(1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or

(2) Is identified as a Radiation Safety Officer on—

(i) A specific medical use license issued by the Commission or Agreement State; or

(ii) A medical use permit issued by a Commission master material licensee.

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

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.

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.

Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

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.

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

Therapeutic dosage means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

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

Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

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.

Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

[69 FR 55737, Sep. 16, 2004; 70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 72 FR 55930 Oct. 1, 2007; 83 FR 33102, Jul. 16, 2018]

§ 35.5 Maintenance of records.

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Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.6 Provisions for the protection of human research subjects.

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(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, before conducting research--

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002]

§ 35.7 FDA, other Federal, and State requirements.

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

§ 35.8 Information collection requirements: OMB approval.

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(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, NRC Form 313, including NRC Form 313A, which licensees may use to provide supplemental information, is approved under control number 3150-0120.

(2) [Reserved]

[67 FR 20370; Apr. 24, 2002, as amended at 70 FR 16361, Mar. 30, 2005; 83 FR 33102, Jul. 16, 2018]

§ 35.10 Implementation.

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(a) A Government agency or a Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required by the Atomic Energy Act of 1954, as amended, must comply with the requirements of this part, including provisions that are specific to licensees, on November 30, 2007. All other persons who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required, must comply with the requirements of this part, including provisions that are specific to licensees, on August 8, 2009, or earlier as noticed by the NRC.

(b) [Reserved]

(c) [Reserved]

(d) If a license condition exempted a licensee from a provision of Part 35 on October 24, 2002, then the license condition continues to exempt the licensee from the requirements in the corresponding provision of §§ 35.1-35.4002.

(e) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(f) A licensee shall continue to comply with any license condition that requires it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until there is a license amendment or renewal that modifies the license condition.

[69 FR 55737, Sep. 16, 2004; 70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007]

§ 35.11 License required.

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(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.

(b) A specific license is not needed for an individual who—

(1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; or

(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

(c)(1) A Government agency or a Federally recognized Indian Tribe, that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use such materials for medical uses until the date of the NRC's final licensing determination, provided that the person submits a medical use license application on or before December 1, 2008.

(2) Except as provided in paragraph (c)(1) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific medical use license is required in paragraph (a) of this section, may continue to use this type of material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license application within 12 months from the

waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[72 FR 55930 Oct. 1, 2007]

§ 35.12 Application for license, amendment, or renewal.

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(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by—

(1) Filing an original NRC Form 313, "Application for 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

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original of either—

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter containing all information required by NRC Form 313; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:

(1) 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;

(2) 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 § 35.1000 medical use;

(3) Any additional specific information on—

(i) Radiation safety precautions and instructions;

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

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) Any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 83 FR 33102, Jul. 16, 2018]

§ 35.13 License amendments.

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A licensee shall apply for and must receive a license amendment—

(a) Before it receives, prepares, or uses byproduct material for a type of use that is permitted under this part, but is not authorized on the licensee's current license issued under this part; except that—

(1) A Government agency or a Federally recognized Indian Tribe licensee who possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 may continue to use such material for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(2) Except as provided in paragraph (a)(1) of this section, all other licensees who possess and use accelerator-produced radioactive material or discrete sources of radium-226 may continue to use those materials for medical uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a medical use license amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(b) Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—

(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a);

(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;

(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and 35.59;

(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist—

(i) On a Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(ii) On a permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy;

(iii) On a permit issued by a Commission master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

(iv) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

(5) A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials 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, and for only those materials and uses performed before these dates.

(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

(d) 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;

(e) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;

(f) Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either § 35.100 or § 35.200 if the change includes 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. Other areas of use where byproduct material is used only in accordance with either § 35.100 or § 35.200 are exempt;

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and

(i) 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.

[70 FR 16361, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007; 83 FR 33102, Jul. 16, 2018]

§ 35.14 Notifications.

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(a) A licensee shall provide the Commission, no later than 30 days after the date that the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist—

(1) A copy of the board certification and, as appropriate, verification of completion of:

(i) Training for the authorized medical physicist under § 35.51(c);

(ii) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300; or

(iii) Device specific training in § 35.690(c) for the authorized user under § 35.600; or

(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.

(b) A licensee shall notify the Commission no later than 30 days after:

(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;

(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c);

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 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

(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 § 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(c) The licensee shall send the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

[68 FR 58805, Oct. 10, 2003; 70 FR 16361, Mar. 20, 2005; 71 FR 15008, Mar. 27, 2006; 72 FR 55930 Oct. 1, 2007; 83 FR 33103, Jul. 16, 2018]

§ 35.15 Exemptions regarding Type A specific licenses of broad scope.

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A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33 of this chapter, is exempt from—

(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical use of byproduct material, as described in § 35.1000;

(b) The provisions of § 35.13(b);

(c) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(d) The provisions of § 35.14(a);

(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

(f) The provisions of § 35.14(b)(5).

(g) The provisions of § 35.49(a).

[72 FR 55931 Oct. 1, 2007; 83 FR 33103, Jul. 16, 2018]

§ 35.18 License issuance.

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(a) The Commission shall issue a license for the medical use of byproduct material if--

(1) The applicant has filed NRC Form 313 "Application for Material License" in accordance with the instructions in § 35.12;

(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(4) The applicant meets the requirements of Part 30 of this chapter.

(b) The Commission shall issue a license for mobile medical service if the applicant:

(1) Meets the requirements in paragraph (a) of this section; and

(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

§ 35.19 Specific exemptions

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The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B—General Administrative Requirements

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§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing--

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

(b) 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.

(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the Commission in accordance with § 35.14(b).

(d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to—

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

[83 FR 33103, Jul. 16, 2018]

§ 35.26 Radiation protection program changes.

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(a) A licensee may revise its radiation protection program without Commission approval if--

(1) The revision does not require a license amendment under § 35.13;

(2) The revision is in compliance with the regulations and the license ;

(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(4) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with § 35.2026.

§ 35.27 Supervision.

[Top of File]

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by § 35.11(b)(1), shall--

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall--

(1) In addition to the requirements in § 19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.

§ 35.40 Written directives.

[Top of File]

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following information—

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

(6) For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) 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

(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: The treatment site, radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and
exposure time (or the total dose); and date.

(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

[67 FR 20370, Apr. 24, 2002 as amended at 68 FR 75389, Dec. 31, 2003; 83 FR 33103, Jul. 16, 2018]

§ 35.41 Procedures for administrations requiring a written directive.

[Top of File]

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material—

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations;

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;

(5) Determining if a medical event, as defined in § 35.3045, has occurred; and

(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.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.2041.

[72 FR 45151, Aug. 13, 2007; 83 FR 33104, Jul. 16, 2018]

§ 35.49 Suppliers for sealed sources or devices for medical use.

[Top of File]

For medical use, a licensee may only use--

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State;

(b) Sealed sources or devices non-commercially transferred from a Part 35 licensee or an Agreement State medical use licensee.

(c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.

[71 FR 15008, Mar. 27, 2006]

§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.

[Top of File]

Except as provided in § 35.57, 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 § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (d) of this section. 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: (1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

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

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

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

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

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

(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and

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

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or an Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct 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 —

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) 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 byproduct 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 (b)(1) and (d) 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

(c)(1) 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 § 35.51(a), has experience with the radiation safety aspects of similar types of use of byproduct 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 (d) of this section; or

(2) 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 byproduct 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 (d) of this section; or

(3) Has experience with the radiation safety aspects of the types of use of byproduct 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 licensee. The individual must also meet the requirements in paragraph (d) of this section.

(d) 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.

[70 FR 16361, Mar. 30, 2005; 71 FR 1926, Jan. 12, 2006; 71 FR 15008, Mar. 27, 2006; 74 FR 33904, Jul. 14, 2009; 76 FR 72085, Nov. 22, 2011; 83 FR 33104, Jul. 16, 2018; 86 FR 43402, Aug. 9, 2021]

§ 35.51 Training for an authorized medical physicist.

[Top of File]

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. 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:

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

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

(i) 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

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and

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

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

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

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

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

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and 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 § 35.51, § 35.57, or equivalent 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.

(c) 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.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55737, Sep. 16, 2004; 70 FR 16362, Mar. 30, 2005; 71 FR 15008, Mar. 27, 2006; 74 FR 33904, Jul. 14, 2009; 83 FR 33105, Jul. 16, 2018]

§ 35.55 Training for an authorized nuclear pharmacist.

[Top of File]

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Is certified by a specialty board whose certification process has been recognized by the 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[70 FR 16362, Mar. 30, 2005; 83 FR 33105, Jul. 16, 2018; 86 FR 43402, Aug. 9, 2021]

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

[Top of File]

(a)(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 § 35.50, § 35.51, or § 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.

(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 § 35.50 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.

(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 § 35.51, for those materials and uses that these individuals performed on or before October 24, 2005.

(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 § 35.50, § 35.51 or § 35.55, 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.

(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct 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.

(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct 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 in accordance with a Commission master material broad scope license 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:

(i) For uses authorized under § 35.100 or § 35.200, 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;

(ii) For uses authorized under § 35.300, 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;

(iii) For uses authorized under § 35.400 or § 35.600, 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

(iv) For uses authorized under § 35.500, 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.

(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.

(c) 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.

[70 FR 16363, Mar. 30, 2005; 72 FR 55931 Oct. 1, 2007; 74 FR 33905, Jul. 14, 2009; 83 FR 33105, Jul. 16, 2018; 86 FR 43402, Aug. 9, 2021]

§ 35.59 Recentness of training.

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

[71 FR 15008, Mar. 27, 2006]

Subpart C--General Technical Requirements

[Top of File]

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material

(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

§ 35.61 Calibration of survey instruments.

[Top of File]

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall--

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

[Top of File]

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by—

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by—

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

(c) For other than unit dosages, this determination must be made by—

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.

(d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

(e) A licensee shall retain a record of the dosage determination required by this section in accordance with § 35.2063.

[72 FR 55931, Oct. 1, 2007]

§ 35.65 Authorization for calibration, transmission, and reference sources.

[Top of File]

(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:

(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;

(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 § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);

(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μCI) or 1000 times the quantities in appendix B of part 30 of this chapter; or

(5) Technetium-99m in amounts as needed.

(b) Byproduct material in sealed sources authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or

(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.

(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (a) or (b) of this section need not list these sources on a specific medical use license.

[71 FR 15009, Mar. 27, 2006; 83 FR 33106, Jul. 16, 2018]

§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.

[Top of File]

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(b) A licensee in possession of a sealed source shall—

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 μCi) of radioactive material in the sample.

(d) A licensee shall retain leak test records in accordance with § 35.2067(a).

(e) If the leak test reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination, the licensee shall—

(1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and

(2) File a report within 5 days of the leak test in accordance with § 35.3067.

(f) A licensee need not perform a leak test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 3.7 MBq (100 μCi) or less of beta or gamma-emitting material or 0.37 MBq (10 μCi) or less of alpha-emitting material;

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.

(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067(b).

§ 35.69 Labeling of vials and syringes.

[Top of File]

Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

§ 35.70 Surveys of ambient radiation exposure rate.

[Top of File]

(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

(b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75.

(c) A licensee shall retain a record of each survey in accordance with § 35.2070.

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

[Top of File]

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

[67 FR 20370, Apr. 24, 2002 as amended at 70 FR 16363, Mar. 30, 2005; 72 FR 45151, Aug. 13, 2007]

[1] The current revision of NUREG–1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

§ 35.80 Provision of mobile medical service.

[Top of File]

(a) A licensee providing mobile medical service shall--

(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;

(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and

(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.

(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.

(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080(a) and (b), respectively.

§ 35.92 Decay-in-storage.

[Top of File]

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

(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(2) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

[72 FR 45151, Aug. 13, 2007]

Subpart D—Unsealed Byproduct Material—Written Directive Not Required

[Top of File]

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55931 Oct. 1, 2007]

§ 35.190 Training for uptake, dilution, and excretion studies.

[Top of File]

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i)

through (c)(1)(ii)(F) of this section; and

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

(b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

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

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.100. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.190, § 35.290, or § 35.390, or equivalent Agreement State requirements; or

(ii) 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 § 35.57, § 35.190, § 35.290, or § 35.390, 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 (c)(1) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 74 FR 33905, Jul. 14, 2009; 83 FR 33106, Jul. 16, 2018]

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

[Top of File]

Except for quantities that require a written directive under § 35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in § 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16363, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 55932 Oct. 1, 2007]

§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

[Top of File]

(a) A licensee may not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section.

(c) 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 paragraph (a) of this section.

(d) 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 § 35.2204.

(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.

[72 FR 55932 Oct. 1, 2007; 83 FR 33107, Jul. 16, 2018]

§ 35.290 Training for imaging and localization studies.

[Top of File]

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

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

(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in § 35.55 or § 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

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

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or

(ii) 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 § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), 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 (c)(1) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 72 FR 45151, Aug. 13, 2007; 74 FR 33905, Jul. 14, 2009; 83 FR 33107, Jul. 16, 2018]

Subpart E—Unsealed Byproduct Material—Written Directive Required

[Top of File]

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—

(a) Obtained from:

(1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or

(2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or

(b) Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

(c) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

(d) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003; 69 FR 55738, Sep. 16, 2004; 71 FR 15009, Mar. 27, 2006; 72 FR 55932 Oct. 1, 2007; 83 FR 33107, Jul. 16, 2018]

§ 35.310 Safety instruction.

[Top of File]

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include—

(1) Patient or human research subject control;

(2) Visitor control, including—

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19324, Apr. 21, 2003]

§ 35.315 Safety precautions.

[Top of File]

(a) For each patient or human research subject who cannot be released under § 35.75, a licensee shall—

(1) Quarter the patient or the human research subject either in—

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;

(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

[Top of File]

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) of this section. 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 be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described

in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

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

(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

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

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) [Reserved]

(G) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under § 35.1000. 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—

(*1*) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

(*2*) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131;[2]

(*3*) Parenteral administration of any 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 than 150 keV, for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, 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

(ii) 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 § 35.57, § 35.390, 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 (b)(1) of this section.

[2] Experience with at least three cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009 ; 83 FR 33107, Jul. 16, 2018; 85 FR 65662, Oct. 16, 2020]

§ 35.392 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).

[Top of File]

Except as provided in § 35.57, 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—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (2) of this section and whose certification process has been recognized by the 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

(b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) 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—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) 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

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (2) 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 § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.392, § 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*); or

(ii) 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 § 35.57, § 35.390, § 35.392, § 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*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 (c)(1) and (2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55738, Sep. 16, 2004; 70 FR 16364, Mar. 30, 2005; 71 FR 15009, Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009; 83 FR 33108, Jul. 16, 2018]

§ 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

[Top of File]

Except as provided in 35.57, 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—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (2) of this section, and whose certification has been recognized by the 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

(b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or

(c)(1) 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—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

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

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) 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 I–131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131 for medical uses authorized under § 35.300. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*); or

(ii) 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 § 35.57, § 35.390, § 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*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 (c)(1) and (2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 68 FR 75389, Dec. 31, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16365, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33905, Jul. 14, 2009; 83 FR 33108, Jul. 16, 2018]

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

[Top of File]

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

(1) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(3), or equivalent Agreement State requirements; or

(2) Is an authorized user under § 35.490, § 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (b) of this section; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.490 or § 35.690, and who meets the requirements in paragraph (b) of this section.

(b) The physician—

(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(*3*). A supervising authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

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

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

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

(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(*3*); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (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 byproduct material requiring a written directive. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.390, § 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, § 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) 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 § 35.57, § 35.390, § 35.396, 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 paragraphs (b)(1) and (2) of this section.

[70 FR 16365, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33108, Jul. 16, 2018]

Subpart F—Manual Brachytherapy

[Top of File]

§ 35.400 Use of sources for manual brachytherapy.

A licensee must use only brachytherapy sources:

(a) 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

(b) 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 § 35.49(a) are met.

[83 FR 33109, Jul. 16, 2018]

§ 35.404 Surveys after source implant and removal.

[Top of File]

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

§ 35.406 Brachytherapy sources accountability.

[Top of File]

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

§ 35.410 Safety instruction.

[Top of File]

In addition to the requirements of § 19.12 of this chapter,

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the--

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

§ 35.415 Safety precautions.

[Top of File]

(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under § 35.75, a licensee shall--

(1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;

(2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and

(3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Dislodged from the patient; and

(2) Lodged within the patient following removal of the source applicators.

(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

§ 35.432 Calibration measurements of brachytherapy sources.

[Top of File]

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have—

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.630(a);

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

§ 35.433 Strontium-90 sources for ophthalmic treatments.

[Top of File]

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

(1) An authorized medical physicist; or

(2) An individual who:

(i) 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

(ii) 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

(iii) 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

(iv) Has documented training in:

(A) The creation, modification, and completion of written directives;

(B) Procedures for administrations requiring a written directive; and

(C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

(b) The individuals who are identified in paragraph (a) of this section must:

(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 § 35.432; and

(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 paragraph (a) 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.

(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

[83 FR 33109, Jul. 16, 2018]

§ 35.457 Therapy-related computer systems.

[Top of File]

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine sealed source positions from radiographic images.

§ 35.490 Training for use of manual brachytherapy sources.

[Top of File]

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(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 Council on Postdoctoral Training of the American Osteopathic Association; and

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

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State 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 Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (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 § 35.400. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.490, or equivalent Agreement State requirements; or

(ii) 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 § 35.57, § 35.490, 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 (b)(1) and (2) of this section.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15010. Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33109, Jul. 16, 2018; 85 FR 65662, Oct. 16, 2020]

§ 35.491 Training for ophthalmic use of strontium-90.

[Top of File]

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) 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—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.57, § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33109, Jul. 16, 2018]

Subpart G—Sealed Sources for Diagnosis

[Top of File]

§ 35.500 Use of sealed sources and medical devices for diagnosis.

(a) 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.

(b) 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.

(c) 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 § 35.49(a) are met.

[83 FR 33110, Jul. 16, 2018]

§ 35.590 Training for use of sealed sources and medical devices for diagnosis.

[Top of File]

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the 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

(b) Is an authorized user for uses listed in § 35.200 or equivalent Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(d) Has completed training in the use of the device for the uses requested.

[70 FR 16366, Mar. 30, 2005; 83 FR 33110, Jul. 16, 2018]

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

[Top of File]

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(a) A licensee must only use sealed sources:

(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

(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 § 35.49(a) are met.

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

(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

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

[83 FR 33110, Jul. 16, 2018]

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

[Top of File]

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

§ 35.605 Installation, maintenance, adjustment, and repair.

[Top of File]

(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a

remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee shall—

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include—

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of—

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d)(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.

(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—

(i) The procedures identified in paragraph (a)(4) of this section; and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.

(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.

[83 FR 33110, Jul. 16, 2018]

§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--

(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(2) Cause the source(s) to be shielded when an entrance door is opened; and

(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall--

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require--

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require--

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source--

(1) Remaining in the unshielded position; or

(2) Lodged within the patient following completion of the treatment.

§ 35.630 Dosimetry equipment.

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(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of

the same radionuclide as the source used at the licensee's facility.

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

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

§ 35.632 Full calibration measurements on teletherapy units.

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(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit--

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.633 Full calibration measurements on remote afterloader units.

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(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit--

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions--

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(3) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--

(1) The output within ±3 percent;

(2) Relative helmet factors;

(3) Isocenter coincidence;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error;

(6) Trunnion centricity;

(7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(8) Helmet microswitches;

(9) Emergency timing circuits; and

(10) Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

§ 35.642 Periodic spot-checks for teletherapy units.

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(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of--

(1) Timer accuracy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and

(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of--

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing and intercom systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, and a copy of the procedures required by paragraph (b), in accordance with § 35.2642.

§ 35.643 Periodic spot-checks for remote afterloader units.

[Top of File]

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit--

(1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(2) Before each patient treatment with a low dose-rate remote afterloader unit; and

(3) After each source installation.

(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of--

(1) Electrical interlocks at each remote afterloader unit room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit's computer; and

(8) Decayed source(s) activity in the unit's computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2643.

§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit--

(1) Monthly;

(2) Before the first use of the unit on a given day; and

(3) After each source installation.

(b) A licensee shall--

(1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(2) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum--

(1) Assure proper operation of--

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

(2) Determine--

(i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);

(ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of--

(1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Timer termination;

(5) Radiation monitors used to indicate room exposures; and

(6) Emergency off buttons.

(e) A licensee shall arrange for the repair of any system identified in paragraph (c) of this section that is not operating properly as soon as possible.

(f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by paragraphs (c) and (d) and a copy of the procedures required by paragraph (b) of this section in accordance with § 35.2645.

§ 35.647 Additional technical requirements for mobile remote afterloader units.

[Top of File]

(a) A licensee providing mobile remote afterloader service shall--

(1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(2) Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of--

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in paragraph (b) of this section, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check

the malfunctioning system.

(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

§ 35.652 Radiation surveys.

[Top of File]

(a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

[Top of File]

(a) 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.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

[83 FR 33110, Jul. 16, 2018]

§ 35.657 Therapy-related computer systems.

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The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

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Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c) of this section. 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:

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

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery,

remote afterloaders and external beam therapy; or

(b)(1) 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—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.690, or equivalent Agreement State requirements, at a medical facility that is authorized to use byproduct materials in § 35.600, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State 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 Council on Postdoctoral of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (2) and (c) 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:

(i) A preceptor authorized user who meets the requirements in § 35.57, § 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) 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 § 35.57, § 35.690, or equivalent 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 (b)(1) and (2) of this section.

(c) 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.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003; 69 FR 55739, Sep. 16, 2004; 70 FR 16366, Mar. 30, 2005; 71 FR 15011, Mar. 27, 2006; 74 FR 33906, Jul. 14, 2009; 83 FR 33110, Jul. 16, 2018; 85 FR 65662, Oct. 16, 2020]

Subpart I—[Reserved]
Subpart J—[Reserved]
Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

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§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

Subpart L—Records

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§ 35.2024 Records of authority and responsibilities for radiation protection programs.

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), 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.

[83 FR 33111, Jul. 16, 2018]

§ 35.2026 Records of radiation protection program changes.

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A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

§ 35.2040 Records of written directives.

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A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

§ 35.2041 Records for procedures for administrations requiring a written directive.

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A licensee shall retain a copy of the procedures required by § 35.41(a) for the duration of the license.

§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.

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A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2061 Records of radiation survey instrument calibrations.

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A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

§ 35.2063 Records of dosages of unsealed byproduct material for medical use.

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(a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years.

(b) The record must contain--

(1) The radiopharmaceutical;

(2) The patient's or human research subject's name, or identification number if one has been assigned;

(3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi);

(4) The date and time of the dosage determination; and

(5) The name of the individual who determined the dosage.

§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.

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(a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

§ 35.2070 Records of surveys for ambient radiation exposure rate.

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A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

[Top of File]

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by--

(1) Using the retained activity rather than the activity administered;

(2) Using an occupancy factor less than 0.25 at 1 meter;

(3) Using the biological or effective half-life; or

(4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

§ 35.2080 Records of mobile medical services.

[Top of File]

(a) A licensee shall retain a copy of each letter that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

§ 35.2092 Records of decay-in-storage.

[Top of File]

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

§ 35.2204 Records of molybdenum-99, strontium-82, and strontium-85 concentrations.

[Top of File]

A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by § 35.204(b) and (c) for 3 years. The record must include:

(a) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or

(b) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

[72 FR 55932 Oct. 1, 2007]

§ 35.2310 Records of safety instruction.

[Top of File]

A licensee shall maintain a record of safety instructions required by §§ 35.310 and 35.410 and the operational and safety instructions required by § 35.610 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.

[83 FR 33111, Jul. 16, 2018]

§ 35.2404 Records of surveys after source implant and removal.

[Top of File]

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

§ 35.2406 Records of brachytherapy source accountability.

[Top of File]

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years.

(b) For temporary implants, the record must include--

(1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include--

(1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

§ 35.2432 Records of calibration measurements of brachytherapy sources.

[Top of File]

(a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source.

(b) The record must include—

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.

[Top of File]

(a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source.

(b) The record must include--

(1) The date and initial activity of the source as determined under § 35.432; and

(2) For each decay calculation, the date and the source activity as determined under § 35.433.

§ 35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

[Top of File]

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

§ 35.2610 Records of safety procedures

[Top of File]

A licensee shall retain a copy of the procedures required by §§ 35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

§ 35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include--

(1) The date;

(2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630;

(3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(4) The names of the individuals who performed the calibration, intercomparison, or comparison.

§ 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.

[Top of File]

(a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years.

(b) The record must include--

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and the instruments used to calibrate the unit(s);

(3) The results and an assessment of the full calibrations;

(4) The results of the autoradiograph required for low dose-rate remote afterloader units; and

(5) The signature of the authorized medical physicist who performed the full calibration.

§ 35.2642 Records of periodic spot-checks for teletherapy units.

[Top of File]

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.642(b) until the licensee no longer possesses the teletherapy unit.

§ 35.2643 Records of periodic spot-checks for remote afterloader units.

[Top of File]

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years.

(b) The record must include, as applicable--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

(3) An assessment of timer accuracy;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.643(b) until the licensee no longer possesses the remote afterloader unit.

§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years.

(b) The record must include--

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(3) An assessment of timer linearity and accuracy;

(4) The calculated on-off error;

(5) A determination of trunnion centricity;

(6) The difference between the anticipated output and the measured output;

(7) An assessment of source output against computer calculations;

(8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(c) A licensee shall retain a copy of the procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

§ 35.2647 Records of additional technical requirements for mobile remote afterloader units.

[Top of File]

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years.

(b) The record must include--

(1) The date of the check;

(2) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(3) Notations accounting for all sources before the licensee departs from a facility;

(4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(5) The signature of the individual who performed the check.

§ 35.2652 Records of surveys of therapeutic treatment units.

[Top of File]

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit.

(b) The record must include--

(1) The date of the measurements;

(2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(4) The signature of the individual who performed the test.

§ 35.2655 Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

[Top of File]

(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the use of the unit.

(b) The record must contain—

(1) The inspector's radioactive materials license number;

(2) The date of inspection;

(3) The manufacturer's name and model number and serial number of both the treatment unit and source;

(4) A list of components inspected and serviced, and the type of service; and

(5) The signature of the inspector.

[83 FR 33111, Jul. 16, 2018]

Subpart M—Reports

[Top of File]

§ 35.3045 Report and notification of a medical event.

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

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—

(i) 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

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) 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—

(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(C) An administration of a dose or dosage to the wrong individual or human research subject;

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A leaking sealed source.

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

(A) 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

(B) 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.

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

(i) 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;

(ii) 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

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) 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

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

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include—

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) 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

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[3] The commercial telephone number of the NRC Operations Center is (301) 816–5100.

[68 FR 58805, Oct. 10, 2003; 76 FR 72085, Nov. 22, 2011; 83 FR 33111, Jul. 16, 2018; 85 FR 33530, Jun. 2, 2020]

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

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(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that--

(1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or

(2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(e) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) 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

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[68 FR 58805, Oct. 10, 2003; 85 FR 33530; Jun. 2, 2020]

§ 35.3067 Report of a leaking source.

[Top of File]

A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, by an appropriate method listed in § 30.6(a) of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

[68 FR 58805, Oct. 10, 2003; 73 FR 5720, Jan. 31, 2008; 79 FR 75739, Dec. 19, 2014]

§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

[Top of File]

(a) 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 § 35.204(a) 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.

(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter 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 paragraph (a) of this section.

[83 FR 33111, Jul. 16, 2018]

Subpart N--Enforcement

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§ 35.4001 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 35.4002 Criminal penalties.

[Top of File]

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.4001, and 35.4002.