TDH
TEXAS DEPARTMENT OF HEALTH

25 TEXAS ADMINISTRATIVE CODE

§289.256

Medical and Veterinary Use of Radioactive Material

Texas Regulations for Control of Radiation

(effective October 1, 2000)

25 TAC §289.256

Medical and Veterinary Use of Radioactive Material
(Continued)

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TEXAS REGISTER FORMAT EXPLANATION

The following example is the outline format used for all agency rules. This explanation will help you locate the different references stated throughout the rule:

§289.xxx = sections are the titles

(a) = subsections are the lowercase letters in parenthesis

(1) = paragraphs are the numbers in parenthesis

(A) = subparagraphs are the UPPERCASE letters in parenthesis

(i) = clauses are the *italicized* lowercase roman numerals in parenthesis

(I) = subclauses are the *italicized* UPPERCASE roman numerals in parenthesis

(-a-) = items are the lowercase letters with hyphens in parenthesis

(-1-) = subitems are the numbers with hyphens in parenthesis

289.252 Licensing of Radioactive Material.

(a) Appendices.

(1) Criteria relating to use of financial tests and parent company…

(A) Financial test.

(*i*) To pass the financial test, the parent company…

(*I*) The parent company shall have:

(-a-) two of the following…:

(-1-) a ratio of total liabilities to…;

FOR EXAMPLE:

When the rule states “paragraph (1) of this subsection”, the rule is referring to paragraph “(1)” within subsection “(a).”
When the rule states “subsection (d) of this section”, the rule is referring to subsection “(d)” within the section, for example, §289.252.

(October 2000)

WHERE CAN THE FORMS REFERENCED WITHIN THE RULE BE FOUND?

Forms that are referenced in this rule can be downloaded from the Bureau of Radiation Control web site at:

www.tdh.state.tx.us/ech/rad/pages/brc.htm

Or call (512) 834-6688 to request a copy of the forms

(October 2000)

§289.256 Medical and Veterinary Use of Radioactive Material.

(a) Purpose. This section establishes requirements for the medical and veterinary use of radioactive material and for the issuance of specific licenses authorizing the medical and veterinary use of radioactive material. Unless otherwise exempted, no person shall receive, possess, use, transfer, own, or acquire radioactive material for medical or veterinary use except as authorized in a license issued in accordance with this section. A person who receives, possesses, uses, transfers, owns, or acquires radioactive material prior to receiving a license is subject to the requirements of this chapter.

(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(2) Veterinarians who receive, possess, use, transfer, own, or acquire radioactive material in the practice of veterinary medicine shall do the following:

(A) comply with the requirements in this subsection and subsections (a), (c), (e)-(g), (h)(1), (i)(2), (j)(2)-(4), (m)-(o), (s), (t), (v), (x), (y)(1)(A), (z)(1)(A), (aa)(1)(A) and (2), (aa)(3)(A)(*ii*) and (*iii*) and (B), (bb)(1)-(4), (bb)(5)(A)(*ii*) and (B), and (bb)(6)-(7) of this section; and

(B) verify that the training and experience specified in subsection (c)(3)(B) of this section has been obtained within the five years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

(c) Definitions. The following words and terms when used in this section shall have the following meaning unless the context clearly indicates otherwise.

(1) Address of use - The building or buildings that are identified on the license and where radioactive material may be prepared, received, used, or stored.

(2) Area of use - A portion of an address of use that has been set aside for the purpose of preparing, receiving, using, or storing radioactive material.

(3) Authorized user - Authorized user is defined as either of the following:

(A) for medical use, a physician licensed by the Texas State Board of Medical Examiners who meets the applicable requirements in subsections (y)-(dd) of this section; or

(B) for veterinary use, a veterinarian licensed by the Texas Board of Veterinary Medical Examiners and certified by the American College of Veterinary Radiology who is authorized for the use of radioactive materials in veterinary medicine.

(4) Brachytherapy - A method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

(5) Brachytherapy sealed source - A sealed 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.

(6) High dose-rate remote afterloader - A device that remotely delivers a dose rate in excess of 1200 rads (12 gray (Gy)) per hour at the point or surface where the dose is prescribed.

(7) Institutional Review Board (IRB) - Any board, committee, or other group formally designated by an institution and approved by the United States Food and Drug Administration to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(8) Low dose-rate remote afterloader - A device that remotely delivers a dose rate of less than or equal to 200 rads (2 Gy) per hour at the point or surface where the dose is prescribed.

(9) Licensed medical physicist - An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in the appropriate specialty.

(10) Management - The chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(11) Manual brachytherapy - A type of brachytherapy in which the sealed sources, for example, seeds and ribbons, are manually inserted either into the body cavities that are in close proximity to a treatment site or directly in the tissue volume.

(12) Medical institution - An organization in which several medical disciplines are practiced.

(13) Medical use - The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user.

(14) Medical event - An event that meets the criteria in subsection (ee)(1) of this section.

(15) Medium dose-rate afterloader - A device that remotely delivers a dose rate greater than 200 rads (2 Gy) and less than or equal to 1200 rads (12 Gy) per hour at the point or surface where the dose is prescribed.

(16) Output - The exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit, a brachytherapy source, a remote afterloader unit, or a gamma stereotactic radiosurgery unit, for a specified set of exposure conditions.

(17) Patient - A human or animal under medical care and treatment.

(18) Preceptor - An individual who provides or directs the training and experience requirements.

(19) Permanent facility - A building or buildings that are identified on the license within the state of Texas and where radioactive material may be prepared, received, used, or stored. This may also include an area or areas where administrative activities related to the license are performed.

(20) Prescribed dosage - The specified activity or range of activity of a radiopharmaceutical as documented in a written directive or in accordance with the directions of the authorized user for procedures in subsections (y) and (z) of this section.

(21) Prescribed dose - Prescribed dose means one of the following:

(A) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

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

(C) for brachytherapy, either the total sealed source strength and exposure time, or the total dose, as documented in the written directive; or

(D) for remote afterloaders, the total dose and dose per fraction as documented in the written directive.

(22) Pulsed dose-rate remote afterloader - A special type of remote afterloading device that uses a single sealed source capable of delivering dose rates greater than 1200 rads (12 Gy) per hour, but is approximately one-tenth of the activity of typical high dose-rate remote afterloader sealed sources and is used to simulate the radiobiology of a low dose rate remote afterloader treatment by inserting the sealed source for a given fraction of each hour.

(23) Sealed source and device registry - The national registry that contains all the registration certificates, generated by both the NRC and the agreement states, that summarize the radiation safety information for sealed sources and devices and describe the licensing and use conditions approved for the product.

(24) Stereotactic radiosurgery - The use of external radiation in conjunction with a guidance device to very precisely deliver a dose to a tissue volume by the use of three-dimensional coordinates.

(25) Technologist - Technologist is defined as either of the following:

(A) in nuclear medicine, a person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician; and/or

(B) in therapy, as described in subsections (bb) and (dd) of this section, a person (radiation therapy technologist or radiation therapist) who delivers courses of radiation therapy as prescribed by a radiation oncologist.

(26) Teletherapy - Therapeutic irradiation in which the sealed source is at a distance from the patient or human or animal research subject.

(27) Therapeutic dosage - The specified activity or range of activity of radioactive material that is intended to deliver a radiation dose to a patient or human or animal research subject for palliative or curative treatment.

(28) Therapeutic dose - A radiation dose delivered from a sealed source containing radioactive material to a patient or human or animal research subject for palliative or curative treatment.

(29) Treatment site - The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(30) Type of use - Use of radioactive material as specified under the following subsections:

(A) training, uptake, and dilution studies in subsection (y) of this section;

(B) imaging and localization studies in subsection (z) of this section;

(C) therapy with unsealed radioactive material in subsection (aa) of this section;

(D) manual brachytherapy with sealed sources in subsection (bb) of this section;

(E) sealed sources for diagnosis in subsection (cc) of this section; and

(F) sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in subsection (dd) of this section.

(31) Unit dosage - A dosage prepared for medical use for administration as a single dosage to a patient or human or animal research subject without any further modification of the dosage after it is initially prepared.

(32) Veterinary use - The intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients under the supervision of an authorized user.

(33) Written directive - An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in subsection (p) of this section.

(d) Provisions for research involving human subjects.

(1) A licensee may only conduct research involving human subjects if medical use of radioactive material for research is authorized on the license.

(2) The licensee may conduct research specified in paragraph (1) of this subsection provided that:

(A) the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects as required by Title 10, Code of Federal Regulations (CFR), §35.6 (Federal Policy); or

(B) the licensee has applied for and received approval of a specific amendment to its license before conducting the research.

(3) Prior to conducting research as specified in paragraph (1) of this subsection, the licensee shall obtain the following:

(A) "informed consent," as defined and described in the Federal Policy, from the human research subjects; and

(B) prior review and approval of the research activities from an IRB as required by Title 45, CFR, Part 46 and Title 21, CFR Part 56, and in accordance with the Federal Policy.

(4) Nothing in this subsection relieves licensees from complying with the other requirements of this chapter.

(e) Implementation.

(1) If a license condition exempted a licensee from a provision of this section or §289.252 of this title on October 1, 2000, then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal that modifies or removes the license condition.

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

(3) Licensees shall continue to comply with any license condition that requires implementation of procedures required by subsection (dd)(4) and (10)-(12) of this section until there is a license amendment or renewal that modifies the license condition.

(f) Specific requirements for the issuance of licenses. In addition to the requirements in §289.252(e) of this title and subsections (j)-(l) of this section, as applicable, a license will be approved if the agency determines that:

(1) the applicant satisfies any applicable special requirement in this section;

(2) qualifications of the designated radiation safety officer (RSO) as specified in subsection (h) of this section are adequate for the purpose requested in the application; and

(3) the following submitted by the applicant is approved:

(A) an operating, safety, and emergency procedures manual to include:

(*i*) specific information on the following:

(*I*) radiation safety precautions and instructions;

(*II*) methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;

(*III*) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(*ii*) any additional information required by this chapter that is requested by the agency to assist in its review of the application; and

(B) qualifications of the following:

(*i*) RSO in accordance with subsection (h) of this section;

(*ii*) authorized user(s) in accordance with subsection (ff)(1) and (c)(3)(B) of this section as applicable to the use(s) being requested; and

(*iii*) radiation safety committee (RSC), if applicable, in accordance with subsection (i) of this section;

(4) the applicant's permanent facility is located in Texas; and

(5) the owner of the property is aware that radioactive material is stored and/or used on the property, if the proposed storage facility is not owned by the applicant. The applicant shall provide a written statement from the owner indicating such.

§289.256(g)

(g) Radiation safety officer.

(1) Every license issued by the agency shall have an RSO designated by the licensee's management. The licensee shall:

(A) establish in writing the authority, duties, and responsibilities of the RSO;

(B) provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative, to perform the following duties:

(*i*) establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with this chapter;

(*ii*) ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, including any corrective measures when levels of radiation exceed established limits;

(*iii*) ensure that individual monitoring devices are used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;

(*iv*) investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;

(*v*) investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by this chapter;

(*vi*) have a thorough knowledge of management policies and administrative procedures of the licensee;

(*vii*) assume control and institute corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(*viii*) ensure that records are maintained as required by this chapter;

(*ix*) ensure the proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and/or transport containers;

(*x*) ensure that inventories are performed in accordance with the activities for which the license application is submitted;

(*xi*) ensure that personnel are complying with this chapter, the conditions of the license, and the operating, safety, and emergency procedures of the licensee; and

(*xii*) serve as the primary contact with the agency; and

(C) have the RSO agree in writing to be responsible for implementing the radiation protection program.

(2) The RSO's documented qualifications shall include training and experience in accordance with subsection (h) of this section.

(3) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO to function as a temporary RSO and to perform the duties of an RSO in accordance with paragraph (1)(A) and (C) of this subsection, provided the licensee takes the actions required in paragraphs (1) and (2) of this subsection, and the RSO meets the qualifications in subsection (h) of this section. Records of qualifications and dates of service shall be maintained in accordance with subsection (ff)(2) of this section for inspection by the agency.

(h) Qualifications for radiation safety officer.

(1) The qualifications for RSOs for licenses for medical or veterinary use of radioactive material without broad-scope authorization shall include the following:

(A) certification by a speciality board whose certification has been recognized by the agency; or

(B) completion of a structured educational program consisting of the following:

(*i*) 200 hours of didactic training in the following areas:

(*I*) radiation physics and instrumentation;

(*II*) radiation protection;

(*III*) mathematics pertaining to the use and measurement of radioactivity;

(*IV*) radiation biology; and

(V) radiation dosimetry; and

(*ii*) one year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, agreement state, or licensing state license that authorizes similar type(s) of use(s) of radioactive material involving the following:

(*I*) shipping, receiving, and performing related radiation surveys;

(*II*) using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

(*III*) securing and controlling radioactive material;

(*IV*) using administrative controls to avoid mistakes in the administration of radioactive material;

(*V*) using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(*VI*) disposing of radioactive material; and

(*iii*) has obtained written documentation, signed by the supervising RSO, specified in clause (*ii*) of this subparagraph, that the individual has satisfactorily completed the requirements in clauses (*i*) and (*ii*) of this subparagraph and has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical and veterinary uses of radioactive material; or

(C) is an authorized user or licensed medical physicist identified on the licensee's radioactive material license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities.

(2) The qualifications for RSOs for licenses for medical use of radioactive material with broad-scope authorization shall include the following:

(A) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and four years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed;

(B) a master's degree in health physics or radiological health and three years of applied health physics experience in a program with radiation safety problems similar to those in the program to be managed;

(C) two years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed and one of the following:

(*i*) doctorate degree in health physics or radiological health;

(*ii*) comprehensive certification by the American Board of Health Physics;

(*iii*) certification by the American Board of Radiology in Medical Nuclear Physics;

(*iv*) certification by the American Board of Science in Nuclear Medicine in Radiation Protection;

(*v*) certification by the American Board of Medical Physics in Medical Health Physics; or

(D) equivalent qualifications as approved by the agency.

(3) The qualifications in paragraphs (1)(A)-(C) and (2)(A)-(D) of this subsection do not apply to individuals who have been adequately trained and designated as RSOs on radioactive material licenses issued prior to October 1, 2000.

(i) Radiation safety committee. Licensees with broad scope authorization and licensees who are authorized for two or more different types of uses of radioactive material under subsections (aa), (bb), and (dd) of this section, or two or more types of units under subsection (dd) of this section shall establish an RSC to oversee all uses of radioactive material permitted by the license.

(1) The RSC for licenses for medical use with broad scope authorization shall be composed of the following individuals as approved by the agency:

(A) authorized users from each type of use of radioactive material authorized on the license;

(B) the RSO;

(C) a representative of nursing service;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) may include other members as the licensee deems appropriate.

(2) The RSC for licenses for medical and veterinary use authorized for two or more different types of uses of radioactive material under subsections (aa), (bb), and (dd) of this section, or two or more types of units under subsection (dd) of this section shall be composed of the following individuals as approved by the agency:

(A) an authorized user of each type of use permitted by the license;

(B) the RSO;

(C) a representative of nursing service, if applicable;

(D) a representative of management who is neither an authorized user nor the RSO; and

(E) may include other members as the licensee deems appropriate.

(3) Duties and responsibilities of the RSC.

(A) For licensees without broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the following:

(*i*) meeting as often as necessary to conduct business but no less than three times a year;

(*ii*) reviewing summaries of the following information presented by the RSO:

(*I*) over-exposures;

(*II*) significant incidents, including spills, contamination, or medical events; and

(*III*) items of non-compliance following an inspection;

(*iii*) reviewing the program for maintaining doses ALARA, and providing any necessary recommendations to ensure doses are ALARA; and

(*iv*) reviewing the audit of the radiation safety program and acting upon the findings.

(B) For licensees with broad scope authorization, the duties and responsibilities of the RSC include, but are not limited to, the items in subparagraph (A) of this paragraph and the following:

(*i*) reviewing the overall compliance status for authorized users;

(*ii*) sharing responsibility with the RSO to conduct periodic audits of the radiation safety program;

(*iii*) developing criteria to evaluate training and experience of new authorized user applicants;

(*iv*) evaluating and approving authorized user applicants who request authorization to use radioactive material at the facility; and

(*v*) reviewing and approving permitted program and procedural changes prior to implementation.

(j) Licenses for medical and veterinarian uses of radioactive material without broad scope authorization. In addition to the requirements of subsection (f) of this section, a license for medical and veterinarian use of radioactive material as described in the applicable subsections (y), (z), and (aa)-(cc) of this section will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsections (y), (z), and (aa)-(cc) of this section as applicable;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses; and

(4) establishment of a RSC in accordance with subsection (i)(2) of this section, if applicable.

(k) License for medical uses of radioactive material with broad scope authorization. In addition to the requirements in subsection (f) of this section, a license for medical use of radioactive material with broad scope authorization will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the review of authorized user qualifications by the RSC is in accordance with subsections (y), (z), and (aa)-(dd) of this section, as applicable;

(2) that the application is for a license authorizing unspecified forms and/or multiple types of radioactive material for medical research, diagnosis, and therapy;

(3) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(4) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(5) that staff has substantial experience in the use of a variety of radioactive material for a variety of human and animal uses;

(6) a full-time RSO meeting the requirements of subsection (h)(2) of this section; and

(7) establishment of a RSC in accordance with subsection (i)(1) of this section.

(l) License for the use of remote control brachytherapy units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements in subsection (f) of this section, a license for the use of remote control brachytherapy (RCB) units, teletherapy units, or gamma stereotactic radiosurgery units will be issued if the agency approves the following documentation submitted by the applicant:

(1) that the physician(s) designated on the application as the authorized user(s) is qualified in accordance with subsection (dd) of this section;

(2) that the radiation detection and measuring instrumentation is appropriate for performing surveys and procedures for the uses involved;

(3) that the radiation safety operating procedures are adequate for the handling and disposal of the radioactive material involved in the uses;

(4) list of radioactive isotopes to be possessed;

(5) the sealed source manufacturer(s) name(s) and the model number(s) of the sealed source(s) to be installed;

(6) the maximum number of sealed sources of each isotope to be possessed, including the activity of each sealed source;

(7) the manufacturer and model name and/or number of the following units, as applicable:

(A) RCB unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) the licensed medical physicist's current Texas license with a specialty in therapeutic radiological physics;

(9) the successful completion of unit-specific, manufacturer-provided training that includes standard clinical and emergency procedures for remote control brachytherapy and gamma stereotactic radiosurgery units for the following personnel:

(A) licensed medical physicist with a specialty in therapeutic radiological physics;

(B) technologists; and

(C) authorized user;

(10) safety procedures and instructions as required by subsection (dd)(4) of this section;

(11) spot check procedures as required by subsection (dd)(10)-(12), as applicable; and

(12) an established RSC in accordance with subsection (i)(1) or (2) of this section if applicable.

(m) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license or deletion of a subsite shall be filed in accordance with §289.252(aa) of this title.

(2) A licensee without broad-scope authorization shall apply for and shall receive a license amendment prior to the following:

(A) receiving or using radioactive material for a type of use that is permitted under this section, but that is not authorized on their current license issued in accordance with this section;

(B) permitting anyone to work as an authorized user or licensed medical physicist under the license;

(C) changing RSOs, except as provided in subsection (g)(3) of this section;

(D) receiving radioactive material in excess of the amount or in a different form, or receiving a different radionuclide than is authorized on the license;

(E) adding or changing the areas identified in the application or on the license;

(F) changing the address(es) of use identified in the application or on the license; and

(G) changing operating, safety, and emergency procedures.

(3) A licensee with broad-scope authorization shall apply for and shall receive a license amendment prior to paragraph (2)(A),(C),(D),(F), and (G) of this subsection.

(n) Records/documents. Each licensee shall maintain copies of the records and documents specified in subsection (ff)(2) of this section at each authorized use site.

(o) Supervision. A licensee may permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, unless prohibited by license condition.

(1) A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall do the following:

(A) instruct the supervised individual in the licensee's written operating, safety, and emergency procedures, written directive procedures, requirements of this chapter, and license conditions with respect to the use of radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written operating, safety, and emergency procedures established by the licensee, requirements of this chapter, and license conditions with respect to the medical use of radioactive material.

(2) A licensee who permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized user, shall do the following:

(A) instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(B) require the supervised individual to follow the instructions of the supervising authorized user regarding the preparation of radioactive material for medical use, the written operating, safety, and emergency procedures established by the licensee, the requirements of this chapter, and license conditions.

(3) A licensee who permits supervised activities under paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(p) Written directives.

(1) A written directive shall be dated and signed by an authorized user prior to administration of sodium iodide I-131 greater than 30 microcuries (μCi)(1.11 MBq), any therapeutic dosage of unsealed radioactive material, or any therapeutic dose of radiation from radioactive material.

(A) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(B) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive or to revise a written directive would jeopardize the patient's health, an oral directive or an oral revision to an existing written directive is acceptable. The information contained in the oral directive or oral revision shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared and signed by the authorized user within 48 hours of the oral directive or oral revision.

(2) The written directive shall contain the patient or human research subject's name and the following information:

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

(B) for an administration of a therapeutic dosage of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;

(C) for gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;

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

(E) for high-dose rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(F) for all other brachytherapy:

(*i*) prior to implantation: the treatment site, the radionuclide, number of sealed sources, and dose; and

(*ii*) after implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sealed sources, total sealed source strength and exposure time or, equivalently, the total dose.

(3) The licensee shall maintain the written directive in accordance with subsection (ff)(2) of this section.

(4) Procedures for administrations requiring a written directive.

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

(*i*) the patient's or human research subject's identity is verified before each administration; and

(*ii*) each administration is in accordance with the written directive.

(B) The procedures required by subparagraph (A) of this paragraph shall, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

(*i*) verification of the identity of the patient or human research subject;

(*ii*) verification that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

(*iii*) a check of both manual and computer-generated dose calculations; and

(*iv*) verification that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsection (dd) of this section.

(q) Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material.

(1) For direct measurements performed in accordance with subsection (r) of this section, the licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

(2) The licensee shall calibrate the instrumentation as specified in paragraph (1) of this subsection in accordance with nationally recognized standards or the manufacturer's instructions.

(3) The calibration required by paragraph (2) of this subsection shall include tests for constancy, accuracy, linearity, and geometry dependence, as appropriate to demonstrate proper operation of the instrument. The tests for constancy, accuracy, linearity, and geometry dependence shall be conducted at the following intervals:

(A) constancy at least once each day prior to assay of patient dosages;

(B) linearity at installation, repair, relocation, and at least quarterly thereafter;

(C) geometry dependence at installation; and

(D) accuracy at installation and at least annually thereafter.

(4) The licensee shall maintain a record of each instrument calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:

(A) model and serial number of the instrument and calibration sources;

(B) dates of the calibration;

(C) results of the calibration; and

(D) name of the individual who performed the calibration.

(r) Determination of dosages of radioactive material for medical use.

(1) Before medical use, the licensee shall perform the following:

(A) record the activity of each dosage; and

(B) determine the activity of each dosage using a dose calibrator, by direct measurement of radioactivity, or a decay correction, based on the activity or activity concentration determined by the following:

(*i*) a manufacturer or preparer licensed in accordance with §289.252(r) of this title, or under an equivalent NRC, agreement state, or licensing state license; 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 the FDA.

(2) For other than unit dosages, this determination shall be made by:

(A) direct measurement of radioactivity; or

(B) combination of direct measurement of radioactivity and mathematical calculations.

(3) Unless otherwise directed by the authorized user, a licensee shall 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%.

(4) A licensee restricted to only unit doses prepared in accordance with §289.252(r) need not comply with the requirements in paragraph (1)(B) of this subsection, unless the administration time of the unit dose deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more.

(5) A licensee shall maintain a record of the dosage determination required by this subsection in accordance with subsection (ff)(2) of this section. The record shall contain the following:

(A) radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical;

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

(C) prescribed dosage;

(D) determined dosage or a notation that the total activity is less than 30 μCi (1.1 MBq);

(E) the date and time of the dosage determination; and

(F) the name of the individual who determined the dosage.

(s) Authorization for calibration and reference sources. Any licensee authorized by subsections (j)-(l) of this section for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(1) sealed sources manufactured and distributed by a person licensed in accordance with §289.252 of this title and that do not exceed 30 millicurie (mCi) (1.11GBq) each;

(2) any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.555 Gbq);

(3) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 μCi (7.4 MBq) or 1000 times the quantities in §289.252(w)(6) of this title;

(4) technetium-99m in amounts as needed; and

(5) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources received, possessed, and transferred. Records of the inventories shall be maintained for inspection by the agency in accordance with subsection (ff)(2) of this section and shall include the quantities and kinds of radioactive material, sealed source identification numbers, location of sealed sources, the dates of the inventory, and the identification of the individual(s) making the record.

(t) Requirements for possession of sealed sources and brachytherapy sealed sources. A licensee in possession of any sealed source or brachytherapy source shall:

(1) follow the radiation safety and handling instructions supplied by the manufacturer and the leakage test requirements in accordance with §289.201(g) of this title.

(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources received, possessed, and transferred. Records of the inventories shall be maintained for inspection by the agency in accordance with subsection (ff)(2) of this section and shall include the quantities and kinds of radioactive material, sealed source identification numbers, location of sealed sources, the dates of the inventory, and the identification of the individual(s) making the record.

(u) Labeling of vials and syringes. Each syringe and vial that contains a radiopharmaceutical shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(v) Surveys for ambient radiation exposure rate.

(1) Except as provided in paragraph (2) of this subsection, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee does not need to perform the surveys required by paragraph (1) of this subsection in an area(s) where patients or human research subjects are confined when they cannot be released in accordance with subsection (w) of this section or an animal that is confined. Once the patient or human or animal research subject is released from confinement, the licensee shall survey with a radiation survey instrument, the area in which the patient or human or animal research subject was confined.

(3) A record of each survey shall be maintained in accordance with subsection (ff)(2) of this section. The record shall include the following:

(A) dates of the survey;

(B) results of the survey;

(C) manufacturer's name and model and serial number of the instrument used to make the survey; and

(D) name of the individual who performed the survey.

(w) Release of individuals containing radioactive drugs or implants containing radioactive material.

(1) The licensee may authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material in accordance with a written directive specified in subsection (p) of this section if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 milliroentgens per hour at a distance of 1 meter from the eye plaque location;

(2) The licensee shall provide the released individual, or the individual's parent or guardian, with written instructions on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). If the TEDE to a breast-feeding infant or child could exceed 0.1 rem (1 mSv), assuming there was no interruption of breast-feeding, the instructions shall also include the following:

(A) guidance on the interruption or discontinuation of breast-feeding; and

(B) information on the potential consequences, if any, of failure to follow the guidance.

(3) The licensee shall maintain a record in accordance with subsection (ff)(2) of this section of each patient released in accordance with paragraph (1) of this subsection. The record shall include the following:

(A) the basis for authorizing the release of an individual; and

(B) the instructions provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv).

(x) Decay-in-storage.

(1) The licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage and dispose of it without regard to its radioactivity if the licensee does the following:

(A) monitors radioactive 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

(B) removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after it has been released.

(2) The licensee shall maintain a record of each disposal permitted under paragraph (1) of this subsection in accordance with subsection (ff)(2) of this section. The record shall include the following:

(A) dates of the disposal;

(B) manufacturer's name and model and serial number of the survey instrument used;

(C) background dose rate;

(D) dose rate measured at the surface of each waste container; and

(E) name of the individual who performed the disposal.

(y) Use of and training for radioactive material for uptake, dilution, and excretion studies that do not require a written directive.

(1) Use of radioactive material for uptake, dilution, and excretion studies. Except for quantities that require a written directive in accordance with subsection (p) of this section, the licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that meets the following:

(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;

(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (2) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;

(C) is obtained from an NRC, agreement state, or licensing state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by the FDA; or

(D) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by the FDA.

(2) Training for uptake, dilution, and excretion studies. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(A) and (I) or (ff)(1)(H) and (I) of this section.

(z) Use of and training for radioactive material for imaging and localization studies that do not require a written directive.

(1) Use of radioactive material for imaging and localization studies. Except for quantities that require a written directive in accordance with subsection (p) of this section, the licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that meets the following:

(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;

(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (4) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;

(C) is obtained from an NRC, agreement state, or licensing 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 the FDA; or

(D) is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

(2) Any licensee who processes and prepares radiopharmaceuticals for human use shall do so according to instructions that are furnished by the manufacturer on the label attached to or in the FDA-accepted instructions in the leaflet or brochure that accompanies the generator or reagent kit or the rules of the practice of pharmacy, as promulgated by the Texas State Board of Pharmacy.

(3) Permissible molybdenum-99 concentration.

(A) The licensee may not administer to humans a radiopharmaceutical containing more than 0.15 μCi of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).

(B) The licensee who uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (1) of this subsection.

(C) If the licensee is required to measure the molybdenum-99 concentration, the licensee shall maintain a record of each measurement in accordance with subsection (ff)(2) of this section. The record shall include the following for each measured elution of technetium-99m:

(*i*) ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m);

(*ii*) times and dates of the measurement; and

(*iii*) name of the individual who made the measurement.

(4) Training for imaging and localization studies. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(B) and (I) or (ff)(1)(H) and (I) of this section.

(aa) Use of and training for unsealed radioactive material for human therapy that requires a written directive or veterinary therapeutic use.

(1) Use of unsealed radioactive material for therapy. A licensee may use any unsealed radioactive material prepared for medical use that requires a written directive in accordance with subsection (p) of this section or veterinary therapeutic use that meets the following:

(A) is obtained from a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing state requirements;

(B) is prepared by a physician who is an authorized user and who meets the requirements specified in paragraph (4) of this subsection, or an individual under the supervision of an authorized user as specified in subsection (o) of this section;

(C) is obtained from an NRC, agreement state, or licensing state licensee for use in research in accordance with an IND application accepted by the FDA; or

(D) is prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

(2) Safety instruction to personnel.

(A) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who have received therapy with a drug containing radioactive material and cannot be released in accordance with subsection (w) of this section or an animal that is confined. The instruction shall be appropriate to the personnel's assigned duties and include the following:

(*i*) patient or human or animal research subject control; and

(*ii*) visitor control to include the following:

(*I*) routine visitation to hospitalized individuals or animals in accordance with §289.202(n) of this title;

(*II*) contamination control;

(*III*) waste control; and

(*IV*) notification of the RSO, or his or her designee, and the authorized user if the patient or the human or animal research subject dies or has a medical emergency.

(B) The licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction. The record shall include the following:

(*i*) list of the topics covered;

(*ii*) date of the instruction or training;

(*iii*) name(s) of the attendee(s); and

(*iv*) name(s) of the individual(s) who provided the instruction.

(3) Safety precautions for patients or human or animal research subjects receiving radiopharmaceutical therapy.

(A) For each patient or human or animal research subject receiving radiopharmaceutical therapy and hospitalized in accordance with subsection (w) of this section or animal that is confined, the licensee shall do the following:

(*i*) provide a private room with a private sanitary facility;

(*ii*) post the patient's or the human or animal research subject's room with a "Radioactive Materials" sign and note on the door and 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

(*iii*) either monitor material and items removed from the patient's or the human or animal 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 such material and items as radioactive waste.

(B) The RSO, or his or her designee, and the authorized user shall be notified immediately if the patient or human or animal research subject has a medical emergency or if the patient dies.

(4) Training for use of radioactive material for therapy that requires a written directive. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(C) and (I) or (ff)(1)(H) and (I) of this section.

(bb) Use of and training for sealed sources for manual brachytherapy.

(1) Use of sealed sources for manual brachytherapy. The licensee shall use only brachytherapy sealed sources for therapeutic medical uses as follows:

(A) as approved in the Sealed Source and Device Registry; or

(B) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA and as approved by the agency.

(2) Surveys after sealed source implants and removal.

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

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

(C) A record of each survey shall be maintained in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the survey;

(*ii*) results of the survey;

(*iii*) manufacturer's name and model and serial number of the instrument used to make the survey; and

(*iv*) name of the individual who performed the survey.

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(3) Brachytherapy sealed sources inventory.

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

(B) Promptly after removing sealed sources from a patient or a human or animal research subject, the licensee shall return brachytherapy sealed sources to a secure storage area.

(C) The licensee shall maintain a record of the brachytherapy sealed source accountability in accordance with subsection (ff)(2) of this section.

(*i*) The following information shall be recorded when temporary implants are removed from storage:

(*I*) number and activity of sealed sources;

(*II*) times and dates;

(*III*) name of the individual who removed them from storage;

(*IV*) location of use; and

(*V*) when returned to storage, the name of the individual who returned them and the information in subclauses (*I*) and (*II*) of this clause.

(*ii*) The following information shall be recorded when permanent implants are removed from storage:

(*I*) number and activity of sealed sources;

(*II*) dates;

(*III*) name of the individual who removed them from storage;

(*IV*) the information in subclauses (*I*)-(*III*) of this clause for all sealed sources not implanted; and

(*V*) the number and activity of sealed sources permanently implanted in the patient or human research subject.

(4) Safety instruction to personnel. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who are undergoing implant therapy and who cannot be released in accordance with subsection (w) of this section or animals that are confined.

(A) The instruction shall be appropriate to the personnel's assigned duties and include the following:

(*i*) size and appearance of brachytherapy sealed sources;

(*ii*) safe handling and shielding instructions;

(*iii*) patient or human research subject control;

(*iv*) visitor control to include visitation to hospitalized individuals in accordance with §289.202(n) of this title; and

(*v*) notification of the RSO, or his or her designee, and an authorized user if the patient or the human or animal research subject dies or has a medical emergency.

(B) A licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction. The record shall include the following:

(*i*) list of the topics covered;

(*ii*) date of the instruction or training;

(*iii*) name(s) of the attendee(s); and

(*iv*) name(s) of the individual(s) who provided the instruction.

(5) Safety precautions for the use of brachytherapy.

(A) For each patient or human or animal research subject who is receiving brachytherapy and cannot be released in accordance with subsection (w) of this section or animals that are confined, the licensee shall:

(*i*) provide a private room with a private sanitary facility;

(*ii*) post the patient's or the human or animal research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human or animal research subject's chart where and how long visitors may stay in the patient's or the human or animal research subject's room; and

(*iii*) have available near each treatment room emergency response equipment to respond to a sealed source that is inadvertently dislodged from the patient or inadvertently lodged within the patient following removal of the sealed source applicators.

(B) The RSO, or his or her designee, and the authorized user shall be notified if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(6) Calibration measurements of brachytherapy sealed sources.

(A) Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2000, the licensee shall do the following:

(*i*) determine the sealed source output or activity using a dosimetry system that meets the requirements of subsection (dd)(6) of this section;

(*ii*) determine sealed source positioning accuracy within applicators; and

(*iii*) use published protocols accepted by nationally recognized bodies to meet the requirements of clauses (*i*) and (*ii*) of this subparagraph.

(B) The licensee may use measurements provided by the sealed source manufacturer that are made in accordance with subparagraph (A) of this paragraph.

(C) The licensee shall mathematically correct the outputs or activities determined in subparagraph (A) of this paragraph for physical decay at intervals consistent with 1.0% physical decay.

(D) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the calibration;

(*ii*) manufacturer's name and model and serial number for the sealed source and instruments used to calibrate the sealed source;

(*iii*) sealed source output or activity;

(*iv*) sealed source positioning accuracy within applicators; and

(*v*) signature of a licensed medical physicist.

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

(A) the sealed 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 radioactive sealed source positions from radiographic images.

(8) Training for use of manual brachytherapy sealed sources.

(A) An authorized user of sealed sources for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(D), (E), and (I) or (ff)(1)(H) and (I) of this section.

(B) An authorized user who is limited to the use of eye applicators shall be a physician who meets the requirements of subsection (ff)(1)(E) and (I) or (ff)(1)(H) and (I) of this section.

(cc) Use of and training for sealed sources for diagnosis.

(1) Use of sealed sources for diagnosis. The licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

(2) Training for use of sealed sources for diagnosis. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(F) and (I) or (ff)(1)(H) and (I) of this section.

(dd) Use of and training for a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(1) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. The licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic units for therapeutic medical uses as follows:

(A) as approved in the Sealed Source and Device Registry; or

(B) in research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA.

(2) Surveys of patients and human research subjects treated with a remote afterloader unit.

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

(B) The licensee shall maintain a record of the surveys in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the survey;

(*ii*) results of the survey;

(*iii*) manufacturer's name and model and serial number of the survey instrument used; and

(*iv*) name of the individual who made the survey.

(3) Installation, maintenance, adjustment, and repair.

(A) Only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source(s) shielding, the sealed source(s) driving unit, or other electronic or mechanical component that could expose the sealed source(s), reduce the shielding around the sealed source(s), or compromise the radiation safety of the unit or the sealed source(s).

(B) Except for low dose-rate remote afterloader units, only a person specifically licensed by the agency, the NRC, an agreement state, or licensing state shall install, replace, relocate, or remove a sealed source or sealed source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.

(C) For a low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, an agreement state, a licensing state, or a licensed medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(D) The licensee shall maintain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with subsection (ff)(2) of this section. For each installation, maintenance, adjustment and repair, the record shall include the dates, description of the service, and name(s) of the individual(s) who performed the work.

(4) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall do the following:

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

(B) permit only individuals approved by the authorized user, RSO, or licensed medical physicist with a specialty in theraputic radiological physics to be present in the treatment room during treatment with the sealed source(s);

(C) prevent dual operation of more than one radiation producing device in a treatment room if applicable;

(D) develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the sealed 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;

(*i*) The procedure required by this paragraph shall include the following:

(*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 licensed medical physicist with a specialty in therapeutic radiological physics, and the RSO to be contacted if the unit or console operates abnormally.

(*ii*) A copy of the procedures required by this paragraph shall be physically located at the unit console.

(E) post instructions at the unit console to inform the operator of the following:

(*i*) the location of the procedures required by subparagraph (D) of this paragraph; and

(*ii*) the names and telephone numbers of the authorized users, the licensed medical physicist with a specialty in therapeutic radiological physics, and the RSO to be contacted if the unit or console operates abnormally;

(F) provide instruction initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the following:

(*i*) procedures identified in subparagraph (D) of this paragraph; and

(*ii*) operating procedures for the unit;

(G) ensure that operators, licensed medical physicists with a specialty in therapeutic radiological physics, and authorized users participate in drills of the emergency procedures, initially and at least annually; and

(H) maintain a record, in accordance with subsection (ff)(2) of this section, of individuals receiving instruction and participating in drills required by subparagraphs (F) and (G) of this paragraph. The record shall include the following:

(*i*) a list of the topics covered;

(*ii*) date of the instruction or drill;

(*iii*) name(s) of the attendee(s); and

(*iv*) name(s) of the individual(s) who provided the instruction.

(5) Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall do the following:

(A) control access to the treatment room by a door at each entrance;

(B) equip each entrance to the treatment room with an electrical interlock system that will do the following:

(*i*) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(*ii*) cause the sealed source(s) to be shielded promptly when an entrance door is opened; and

(*iii*) prevent the sealed source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the sealed source(s) "on-off" control is reset at the console;

(C) 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, 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 sealed sources are placed within the patient's or human research subject's body, only conduct treatments that allow for expeditious removal of a decoupled or jammed sealed source;

(F) in addition to the requirements specified in subparagraph (B) of this paragraph, require the following for low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units:

(*i*) a licensed medical physicist with a specialty in therapeutic radiological physics, 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, be physically present during the initiation of all patient treatments involving the unit; and

(*ii*) a licensed medical physicist with a specialty in therapeutic radiological physics, and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the sealed source applicator(s) in the event of an emergency involving the unit, be immediately available during continuation of all patient treatments involving the unit;

(G) in addition to the requirements specified in subparagraphs (A) and (B) of this paragraph, require the following for high dose-rate remote afterloader units:

(*i*) an authorized user and a licensed medical physicist with a specialty in therapeutic radiological physics be physically present during the initiation of all patient treatments involving the unit; and

(*ii*) a licensed medical physicist with a specialty in therapeutic radiological physics, 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, be physically present during continuation of all patient treatments involving the unit;

(H) in addition to the requirements specified in subparagraphs (A) and (B) of this paragraph, require that an authorized user and a licensed medical physicist with a specialty in therapeutic radiological physics be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units;

(I) notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies; and

(J) have applicable emergency response equipment available near each treatment room to respond to a sealed source that inadvertently remains in the unshielded position or inadvertently lodges within the patient following completion of the treatment.

(6) Dosimetry equipment.

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

(*i*) The system shall have been calibrated using a system or sealed 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 shall have been performed within the previous two years and after any servicing that may have affected system calibration.

(*ii*) The system shall have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system shall 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 shall have indicated that the calibration factor of the licensee's system had not changed by more than 2.0%. 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 unit, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sealed sources of the same radionuclide as the sealed source used at the licensee's facility.

(B) The licensee shall have available for use a dosimetry system 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 subparagraph (A) of this paragraph. This comparison shall 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 subparagraph (A) of this paragraph.

(C) The licensee shall maintain a record of each calibration, intercomparison, and comparison of dosimetry equipment in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the calibration;

(*ii*) model and serial numbers of the instruments that were calibrated, intercompared, or compared;

(*iii*) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

(*iv*) the names of the individuals who performed the calibration, intercomparison, or comparison.

(7) Full calibration measurements on teletherapy units.

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(A) The licensee shall perform full calibration measurements on each teletherapy unit as follows:

(*i*) before the first medical use of the unit; and

(*ii*) before medical use under the following conditions:

(*I*) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(*II*) following replacement of the sealed 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 sealed source or major repair of the components associated with the sealed source exposure assembly; and

(*iii*) at intervals not to exceed one year.

(B) Full calibration measurements shall include determination of the following:

(*i*) output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;

(*ii*) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(*iii*) uniformity of the radiation field and its dependence on the orientation of the useful beam;

(*iv*) timer constancy and linearity over the range of use;

(*v*) "on-off" error; and

(*vi*) the accuracy of all distance measuring and localization devices in medical use.

(C) The licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(*i*) of this paragraph may be made using a dosimetry system that indicates relative dose rates.

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

(E) The licensee shall mathematically correct the outputs determined in subparagraph (B)(*i*) of this paragraph for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.

(F) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by paragraph (E) of this subsection shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(G) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the calibration;

(*ii*) manufacturer's name and model and serial number for the unit's sealed source;

(*iii*) instruments used to calibrate the unit;

(*iv*) results and an assessment of the full calibration; and

(*v*) signature of the licensed medical physicist with a specialty in therapeutic radiological physics who performed the full calibration.

(8) Full calibration measurements on remote afterloader units.

(A) The licensee shall perform full calibration measurements on each remote afterloader unit as follows:

(*i*) before the first medical use of the unit; and

(*ii*) before medical use under the following conditions:

(*I*) following replacement of the sealed source;

(*II*) following reinstallation of the unit in a new location outside the facility;

(*III*) following any repair of the unit that includes removal of the sealed source or major repair of the components associated with the sealed source exposure assembly;

(*iii*) at intervals not to exceed three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sealed sources whose half-life exceeds 75 days; and

(*iv*) at intervals not to exceed one year for low dose-rate afterloader units.

(B) Full calibration measurements shall include, as applicable, determination of the following:

(*i*) the output within plus or minus 5.0%;

(*ii*) sealed source positioning accuracy to within plus or minus 1 mm;

(*iii*) sealed source retraction with backup battery upon power failure;

(*iv*) length of the sealed source transfer tubes;

(*v*) timer accuracy and linearity over the typical range of use;

(*vi*) length of the applicators; and

(*vii*) function of the sealed source transfer tubes, applicators, and transfer tube-applicator interfaces.

(C) A licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output.

(D) A licensee shall make full calibration measurements required by subparagraph (A) of this paragraph 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 subparagraph (B) of this paragraph, a licensee shall perform an autoradiograph of the sealed source(s) to verify inventory and sealed source(s) arrangement at intervals not to exceed three months.

(F) For low dose-rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made in accordance with subparagraphs (A)-(E) of this paragraph.

(G) The licensee shall mathematically correct the outputs determined in subparagraph (B)(*i*) of this paragraph for physical decay at intervals consistent with 1.0% physical decay.

(H) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by subparagraph (G) of this paragraph shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(I) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. In addition to the items in paragraph (7)(G) of this subsection, the record shall also include results of the autoradiograph required for low dose-rate remote afterloader units.

(9) Full calibration measurements on gamma stereotactic radiosurgery units.

(A) The licensee shall perform full calibration measurements on each gamma stereotactic radiosurgery unit as follows:

(*i*) before the first medical use of the unit;

(*ii*) before medical use under the following conditions:

(*I*) whenever spot check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(*II*) following replacement of the sealed sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location;

(*III*) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sealed sources or major repair of the components associated with the sealed source exposure assembly; and

(*iii*) at intervals not to exceed one year.

(B) Full calibration measurements shall include determination of the following:

(*i*) the output within plus or minus 3.0%;

(*ii*) relative helmet factors;

(*iii*) isocenter coincidence;

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

(*v*) "on-off" error;

(*vi*) trunnion centricity;

(*vii*) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit "off";

(*viii*) helmet microswitches;

(*ix*) emergency timing circuits; and

(*x*) stereotactic frames and localizing devices (trunnions).

(C) The licensee shall use the dosimetry system described in paragraph (6)(A) of this subsection to measure the output for one set of exposure conditions. The remaining radiation measurements required in subparagraph (B)(*i*) of this paragraph may be made using a dosimetry system that indicates relative dose rates.

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

(E) The licensee shall mathematically correct the outputs determined in subparagraph (B)(*i*) of this paragraph at intervals not to exceed one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.

(F) Full calibration measurements required by subparagraph (A) of this paragraph and physical decay corrections required by subparagraph (E) of this paragraph shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(G) The licensee shall maintain a record of each calibration in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the calibration;

(*ii*) manufacturer's name and model and serial number for the unit's sealed source;

(*iii*) instruments used to calibrate the unit;

(*iv*) results and an assessment of the full calibration; and

(*v*) signature of the licensed medical physicist with a specialty in therapeutic radiological physics who performed the full calibration.

(10) Periodic spot checks for teletherapy units.

(A) The 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 the following:

(*i*) timer constancy and linearity over the range of use;

(*ii*) “on-off” error;

(*iii*) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(*iv*) the accuracy of all distance measuring and localization devices used for medical use;

(*v*) the output for one typical set of operating conditions measured with the dosimetry system described in paragraph (6)(A) of this subsection; and

(*vi*) the difference between the measurement made in subparagraph (A)(*v*) of this section and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.

(B) The licensee shall perform measurements required by subparagraph (A) of this paragraph in accordance with procedures established by a licensed medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.

(C) The 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 sealed source installation to assure proper operation of the following:

(*i*) electrical interlocks at each teletherapy room entrance;

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

(*iii*) sealed source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(*iv*) viewing and intercom systems;

(*v*) treatment room doors from inside and outside the treatment room; and

(*vi*) electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(D) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(E) If the results of the checks required in subparagraph (C) of this paragraph indicate the malfunction of any system, the licensed medical physicist with a specialty in therapeutic radiological physics shall immediately notify the licensee and the 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) The licensee shall maintain a record of each spot check required by subparagraphs (A) and (D) of this paragraph, in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the spot-check;

(*ii*) manufacturer's name and model and serial number for the teletherapy unit, and sealed source and instrument used to measure the output of the teletherapy unit;

(*iii*) assessment of timer linearity and constancy;

(*iv*) calculated "on-off" error;

(*v*) determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(*vi*) the determined accuracy of each distance measuring and localization device;

(*vii*) the difference between the anticipated output and the measured output;

(*viii*) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each sealed source exposure indicator light, and the viewing and intercom system and doors;

(*ix*) name of the individual who performed the periodic spot-check; and

(*x*) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.

(11) Periodic spot checks for remote afterloader units.

(A) The licensee shall perform spot checks of each remote afterloader facility and on each unit as follows:

(*i*) at the beginning of each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

(*ii*) before each patient treatment with a low dose-rate remote afterloader unit; and

(*iii*) after each sealed source installation.

(B) The licensee shall perform the measurements required by subparagraph (A) of this paragraph in accordance with written procedures established by a licensed medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.

(C) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(D) To satisfy the requirements of subparagraph (A) of this paragraph, spot checks shall, at a minimum, assure proper operation of the following:

(*i*) electrical interlocks at each remote afterloader unit room entrance;

(*ii*) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(*iii*) viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(*iv*) emergency response equipment;

(*v*) radiation monitors used to indicate the sealed source position;

(*vi*) timer accuracy;

(*vii*) clock (date and time) in the unit's computer; and

(*viii*) decayed sealed source(s) activity in the unit's computer.

(E) If the results of the checks required in subparagraph (D) of this paragraph indicate the malfunction of any system, the 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) The licensee shall maintain a record, in accordance with subsection (ff)(2) of this section, of each check required by subparagraph (A) of this paragraph. The record shall include the following, as applicable:

(*i*) dates of the spot-check;

(*ii*) manufacturer's name and model and serial number for the remote afterloader unit and sealed source;

(*iii*) an assessment of timer accuracy;

(*iv*) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom systems, clock, and decayed sealed source activity in the unit's computer;

(*v*) name of the individual who performed the periodic spot-check; and

(*vi*) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.

(12) Periodic spot checks for gamma stereotactic radiosurgery units.

(A) The licensee shall perform spot checks of each gamma stereotactic radiosurgery facility and on each unit as follows:

(*i*) monthly;

(*ii*) at the beginning of each day of use; and

(*iii*) after each source installation.

(B) The licensee shall perform the measurements required by subparagraph (A) of this paragraph in accordance with written procedures established by a licensed medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements.

(C) The licensee shall have a licensed medical physicist with a specialty in therapeutic radiological physics review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(D) To satisfy the requirements of subparagraph (A)(*i*) of this paragraph, spot checks shall, at a minimum, achieve the following by:

(*i*) assurance of proper operation of these items:

(*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); and

(*ii*) determination of the following:

(*I*) the output for one typical set of operating conditions measured with the dosimetry system described in paragraph (6)(A) of this subsection;

(*II*) the difference between the measurement made in subclause (*I*) of this clause and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay;

(*III*) sealed source output against computer calculation;

(*IV*) timer accuracy and linearity over the range of use;

(*V*) "on-off" error; and

(*VI*) trunnion centricity.

(E) To satisfy the requirements of subparagraph (A)(*ii*) and (*iii*) of this paragraph, spot checks shall assure proper operation of the following:

(*i*) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(*ii*) sealed source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(*iii*) viewing and intercom systems;

(*iv*) timer termination;

(*vi*) radiation monitors used to indicate room exposures; and

(*vii*) emergency “off” buttons.

(F) The licensee shall arrange for prompt repair of any system identified in subparagraph (D) of this paragraph that is not operating properly.

(G) If the results of the checks required in subparagraph (D) of this paragraph indicate the malfunction of any system, the 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.

(H) The licensee shall retain a record of each check required by subparagraphs (D) and (E) of this paragraph in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of the spot check;

(*ii*) manufacturer's name and model and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(*iii*) an assessment of timer linearity and accuracy;

(*iv*) the calculated “on-off” error;

(*v*) a determination of trunnion centricity;

(*vi*) the difference between the anticipated output and the measured output;

(*vii*) an assessment of sealed source output against computer calculations;

(*viii*) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency “off” buttons, electrical interlocks, sealed source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions);

(*ix*) the name of the individual who performed the periodic spot check; and

(*x*) the signature of the licensed medical physicist with a specialty in therapeutic radiological physics who reviewed the record of the spot check.

(13) Additional technical requirements for mobile remote afterloader units.

(A) The licensee providing mobile remote afterloader service shall do the following:

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

(*ii*) account for all sealed sources before departure from a client's address of use.

(B) In addition to the periodic spot checks required by paragraph (11) of this subsection, the licensee shall perform checks on each remote afterloader unit before medical use at each address of use. At a minimum, checks shall be made to verify the operation of the following:

(*i*) electrical interlocks on treatment area access points;

(*ii*) sealed source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(*iii*) viewing and intercom systems;

(*iv*) applicators, sealed source transfer tubes, and transfer tube-applicator interfaces;

(*v*) radiation monitors used to indicate room exposures;

(*vi*) sealed source positioning (accuracy); and

(*vii*) radiation monitors used to indicate whether the sealed source has returned to a safe shielded position.

(C) In addition to the requirements for checks in subparagraph (B) of this paragraph, the 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 subparagraph (B) of this paragraph indicate the malfunction of any system, the 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) The licensee shall retain a record, in accordance with subsection (ff)(2) of this section, of each check required by subparagraph (B) of this paragraph. The record shall include the following:

(*i*) dates of the check;

(*ii*) manufacturer's name and model and serial number of the remote afterloader unit;

(*iii*) notations accounting for all sealed sources before the licensee departs from a facility;

(*iv*) notations indicating the operability of each entrance door electrical interlock, radiation monitors, sealed source exposure indicator lights, viewing and intercom system, applicators and sealed source transfer tubes, and sealed source positioning accuracy; and

(*v*) the signature of the individual who performed the check.

(14) Radiation surveys.

(A) In addition to the survey requirement in §289.202(p) of this title, a person licensed to use sealed sources in this subsection shall make surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main sealed source safe with the sealed source(s) in the shielded position do not exceed the levels stated in the Registry.

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

(C) The licensee shall retain a record, in accordance with subsection (ff)(2) of this section, of the radiation surveys required by subparagraph (A) of this paragraph. The record shall include:

(*i*) dates of the measurements;

(*ii*) manufacturer's name and model and serial number of the treatment unit, sealed source, and instrument used to measure radiation levels;

(*iii*) each dose rate measured around the sealed source while the unit is in the "off" position and the average of all measurements; and

(*iv*) the signature of the individual who performed the test.

(15) Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

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

(B) This inspection and servicing may only be performed by persons specifically licensed to do so by the agency, the NRC, an agreement state, or licensing state.

(C) The licensee shall keep a record of the inspection and servicing in accordance with subsection (ff)(2) of this section. The record shall include the following:

(*i*) dates of inspection;

(*ii*) manufacturer's name and model and serial number of both the treatment unit and the sealed source;

(*iii*) a list of components inspected and serviced, and the type of service; and

(i*v*) the radioactive material license number and the signature of the individual performing the inspection.

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

(A) the sealed 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.

(17) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. An authorized user of radiopharmaceuticals for the uses authorized in paragraph (1) of this subsection shall be a physician who meets the requirements of subsection (ff)(1)(G) and (I) or (ff)(1)(H) and (I) of this section.

(ee) Report and notification of a medical event.

(1) The licensee shall report any event, except for events that result from intervention by a patient or human research subject, in which the administration of radioactive material, or radiation from radioactive material, results in the following:

(A) a dose that differs from the prescribed dose by more than 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin and either:

(*i*) the total dose delivered differs from the prescribed dose by 20% or more;

(*ii*) the total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range; or

(*iii*) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

(B) a dose that exceeds 5 rem (0.05 Sv) effective dose equivalent, 50 rem (0.5 Sv) to an organ or tissue, or 50 rem (0.5 Sv) shallow dose equivalent to the skin from any of the following:

(*i*) an administration of a wrong radioactive drug containing radioactive material;

(*ii*) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(*iii*) an administration of a dose or dosage to the wrong individual or human research subject;

(*iv*) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(*v*) a leaking sealed source.

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

(2) The licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material, or radiation from radioactive material, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the agency within 15 days after discovery of the medical event. The written report shall include the following, excluding the individual's name or any other information that could lead to identification of the individual:

(A) the licensee's name and radioactive material license number;

(B) the name of the prescribing physician;

(C) a brief description of the medical event;

(D) why the event occurred;

(E) the effect, if any, on the individual(s) who received the administration;

(F) actions, if any, that have been taken, or are planned, to prevent recurrence;

(G) whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(H) if there was notification, what information was provided.

(5) The licensee shall notify 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 judgement, 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 shall 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 subsection, 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 the written description if requested.

(6) 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.

(7) The licensee shall maintain a record of the medical event in accordance with subsection (ff)(2) of this section. A copy of the record shall be provided to the referring physician if other than the licensee. The record shall contain the following:

(A) licensee's name and radioactive material license number;

(B) names of the individuals involved;

(C) the identification number of the individual who is the subject of the medical event;

(D) brief description of the event and why it occurred;

(E) the effect, if any, on the individual; and

(F) the actions, if any, taken, or planned, to prevent recurrence; and

(G) whether the licensee notified the individual or the individual's responsible relative or guardian, and if not, whether the failure to notify was based on guidance from the referring physician.

(8) The licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(9) The licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast feeding individual that:

(A) is greater than 5 rem (50 mSv) TEDE; or

(B) has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(10) The licensee shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (8) or (9) of this subsection.

(11) The licensee shall submit a written report to the agency no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (8) or (9) of this subsection. The written report shall include the items in paragraph (4)(A)-(F) of this subsection, excluding the individual's or child's name or any other information that could lead to identification of the individual or child.

(12) The licensee shall notify 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 in accordance with paragraphs (8) or (9) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgement, telling the mother would be harmful.

(13) To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate.

(14) 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.

(15) If notification was made in accordance with paragraphs (12) and (13) of this subsection, the licensee shall also furnish, within 15 days after discovery of the event, a written report to the mother or responsible relative or guardian, by sending either of the following:

(A) a copy of the report that was submitted to the agency; or

(B) a brief description of both the event and the consequences as they may affect the embryo/fetus or nursing child.

(16) The licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with subsection (ff)(2) of this section. The record shall contain items in paragraph (7)(A) of this subsection.

(ff) Appendices.

(1) Acceptable training and experience for medical uses of radioactive material.

(A) Training for uptake, dilution, and excretion studies.

(*i*) The licensee shall require the authorized user of radiopharmaceuticals for uptake, dilution, and excretion studies to be a physician who:

(*I*) is certified in:

(-a-) nuclear medicine by the American Board of Nuclear Medicine (ABNM);

(-b-) diagnostic radiology or radiology by the American Board of Radiology (ABR);

(-c-) diagnostic radiology or radiology by the American Osteopathic Board of Radiology (AOBR);

(-d-) nuclear medicine by the Royal College of Physicians and Surgeons of Canada (RCPSC); or

(-e-) nuclear medicine by the American Osteopathic Board of Nuclear Medicine (AOBNM); or

(*II*) has successfully completed classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals and supervised clinical experience as follows:

(-a-) 40 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiation biology; and

(-5-) radiopharmaceutical chemistry; and

(-b-) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

(-1-) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(-2-) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(-3-) administering dosages to patients and using syringe radiation shields;

(-4-) collaborating with the authorized user in the interpretation of radioisotope test results; and

(-5-) patient follow-up; or

(-c-) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the Council on Postdoctoral Training of the American Osteopathic Association (COPT-AOA) and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in this subclause.

(*ii*) Training in all the topics identified in clause (*i*)(*II*)(-a-) of this subparagraph, which is not a part of a residency program as in clause (*i*)(*II*)(-c-) of this subparagraph, shall be obtained in an ACGME- or COPT-AOA-accredited medical teaching institution. The 40 hours of classroom and laboratory training in clause (*i*)(*II*)(-a-) of this subparagraph shall have been initiated prior to completion of the clinical experience in clause (*i*)(*II*)(-b-) of this subparagraph. The clinical experience described in clause (*i*)(*II*)(-b-) of this subparagraph shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures or by an authorized physician in an ACGME- or COPT-AOA- accredited medical teaching institution.

(*iii*) Notwithstanding the requirements of clauses (*i*) and (*ii*) of this subparagraph, proof of alternative training that includes the topics and hours listed in subparagraph (B)(*i*)(*II*) of this paragraph may be accepted on a case-by-case basis if the agency, after providing the Medical Committee of the Texas Radiation Advisory Board with the opportunity to review and comment, determines that the alternative training would give an equal or greater level of training to the standards in clauses (*i*) and (*ii*) of this subparagraph.

(B) Training for imaging and localization studies.

(*i*) The licensee shall require the authorized user of radiopharmaceuticals for imaging and localization studies to be a physician who:

(*I*) is certified in:

(-a-) nuclear medicine by the ABNM;

(-b-) diagnostic radiology or radiology by the ABR;

(-c-) diagnostic radiology or radiology by the AOBR;

(-d-) nuclear medicine by the RCPSC; or

(-e-) nuclear medicine by the AOBNM; or

(*II*) has successfully completed classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

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(-a-) 200 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiopharmaceutical chemistry; and

(-5-) radiation biology; and

(-b-) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(-1-) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(-2-) calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(-3-) calculating and safely preparing patient dosages;

(-4-) using administrative controls to prevent the misadministration of byproduct material;

(-5-) using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(-6-) eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(-c-) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

(-1-) examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(-2-) selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(-3-) administering dosages to patients and using syringe radiation shields;

(-4-) collaborating with the authorized user in the interpretation of radioisotope test results; and

(-5-) patient follow-up; or

(-d-) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the ACGME or the COPT-AOA and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in this subclause.

(*ii*) Training in all the topics identified in clause (*i*)(*II*)(-a-) of this subparagraph, which is not a part of a residency program as in clause (*i*)(*II*)(-d-) of this subparagraph, shall be obtained in a medical teaching institution that provides appropriate training programs that have been accredited by the ACGME or the COPT-AOA. The 200 hours of classroom and laboratory training in clause (*i*)(*II*)(-a-) of this subparagraph shall have been initiated prior to completion of the work and clinical experience in clauses (*i*)(*II*)(-b-) and (-c-) of this subparagraph. The work and clinical experience described in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures or by a licensed authorized physician in a medical teaching institution that also provides appropriate training programs that have been accredited by the ACGME or the COPT-AOA. The experience in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph may be obtained concurrently.

(*iii*) Classroom and laboratory training identified in clause (*i*)(*II*) (-a-) of this subparagraph that was initiated before October 1, 1995, and completed by October 1, 1997, will be accepted if it is obtained in an accredited medical school, a federal teaching hospital, or a training program for medical use of radioactive material that has been accepted by the agency, NRC, or another agreement state.

(*iv*) Notwithstanding the requirements of clauses (*i*) and (*ii*) of this subparagraph, proof of alternative training that includes the topics and hours listed in clause (*i*)(*II*) of this subparagraph may be accepted on a case-by-case basis if the agency, after providing the Medical Committee of the Texas Radiation Advisory Board with the opportunity to review and comment, determines that the alternative training would give an equal or greater level of training to the standards in clauses (*i*) and (*ii*) of this subparagraph.

(C) Training for the therapeutic use of radiopharmaceuticals.

(*i*) The licensee shall require the authorized user of radiopharmaceuticals for therapeutic use to be a physician who:

(*I*) is certified in:

(-a-) nuclear medicine by the ABNM;

(-b-) radiology or therapeutic radiology by the ABR;

(-c-) therapeutic radiology or radiology by the AOBR;

(-d-) nuclear medicine by the RCPSC; or

(-e-) nuclear medicine by the AOBNM; or

(*II*) has classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals and supervised clinical experience as follows:

(-a-) 80 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiation biology; and

(-b-) supervised clinical experience under the supervision of an authorized physician user for the type of therapy authorization requested from the following list:

(-1-) use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism in 10 individuals;

(-2-) use of iodine-131 for treatment of thyroid carcinoma in three individuals;

(-3-) use of colloidal phosphorus-32 for intracavitary treatment in three individuals;

(-4-) use of phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastasis in three individuals;

(-5-) use of colloidal gold-198 for intracavitary treatment in three individuals; or

(-6-) use of radiopharmaceuticals not listed in subitems (-1-) through (-5-) of this item for therapeutic treatment in three individuals; or

(-7-) has successfully completed a six-month training program in nuclear medicine as part of a residency program that has been accredited by the ACGME or the COPT-AOA and that included classroom and laboratory training, work experience and supervised clinical experience in all the topics identified in this subclause.

(*ii*) Training in all the topics identified in clause (*i*)(*II*) of this subparagraph, which is not a part of a residency program as in clause (*i*)(*II*)(-b-) of this subparagraph, shall be obtained in a medical teaching institution accredited by the ACGME or the COPT-AOA.

(D) Training for use of brachytherapy sealed sources (except for beta applicators - See subparagraph (E) of this paragraph).

(*i*) The licensee shall require the authorized user of a brachytherapy sealed source to be a physician who:

(*I*) is certified in:

(-a-) therapeutic radiology, radiation oncology, or radiology by the ABR; or

(-b-) therapeutic radiology, radiation oncology, or radiology by the AOBR; or

(-c-) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(-d-) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(*II*) is in the active practice of therapeutic radiology, has had classroom training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sealed sources, and supervised clinical experience as follows:

(-a-) 200 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiation biology; and

(-b-) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(-1-) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(-2-) checking survey meters for proper operation;

(-3-) preparing, implanting, and removing sealed sources;

(-4-) maintaining running inventories of material on hand;

(-5-) using administrative controls to prevent the misadministration of byproduct material; and

(-6-) using emergency procedures to control byproduct material; and

(-c-) three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the ACGME or the COPT-AOA, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(-1-) examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(-2-) selecting the proper brachytherapy sealed sources and dose and method of administration;

(-3-) calculating the dose; and

(-4-) post-administration follow-up and review of case histories in collaboration with the authorized user.

(*ii*) Training in all the topics identified in clause (*i*)(*II*)(-a-) of this subparagraph shall be accredited by the ACGME or the COPT-AOA. The clinical experience described in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph should be supervised by a physician licensed to use brachytherapy sealed sources. The experience in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph may be obtained concurrently.

(E) Training for ophthalmic use of strontium-90.

(*i*) The licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who:

(*I*) is certified in:

(-a-) therapeutic radiology, radiation oncology, or radiology by the ABR;

(-b-) therapeutic radiology, radiation oncology, or radiology by the AOBR;

(-c-) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(-d-) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(*II*) is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(-a-) 24 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiation biology; and

(-b-) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(-1-) examination of each individual to be treated;

(-2-) calculation of the dose to be administered;

(-3-) administration of the dose; and

(-4-) follow-up and review of each individual's case history.

(*ii*) Training in all the topics identified in clause (*i*)(*II*)(-a-) of this subparagraph shall be obtained in a medical teaching institution or shall be accredited by the ACGME or the COPT-AOA. The clinical experience described in clause (*i*)(*II*)(-b-) of this subparagraph shall be supervised by a physician licensed for the use of sealed sources in therapy.

(F) Training for use of sealed sources for diagnosis.

(*i*) The licensee shall require the authorized user of a sealed source in the devices listed in clause (*ii*) of this subparagraph, to be a physician, dentist, or podiatrist who:

(*I*) is certified in:

(-a-) therapeutic radiology, diagnostic radiology, radiation oncology, or radiology by the ABR;

(-b-) nuclear medicine by the ABNM;

(-c-) diagnostic radiology or radiology by the AOBR; or

(-d-) nuclear medicine by the RCPSC; or

(-e-) nuclear medicine by the AOBNM; or

(*II*) has had eight hours of classroom and laboratory training in radioisotope handling techniques specifically applicable to the use of the device that includes:

(-a-) radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(-b-) radiation biology;

(-c-) radiation protection; and

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

(*ii*) The following sealed sources shall be used in accordance with the manufacturer's radiation safety and handling instructions:

(*I*) iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(*II*) iodine-125 as a sealed source in a portable imaging device.

(*iii*) Training in all the topics identified in clause (*i*)(*II*) of this subparagraph shall be obtained in a medical teaching institution or shall be accredited by the ACGME or the COPT-AOA. The clinical experience shall be supervised by a physician, dentist, or podiatrist licensed to use the devices.

(G) Training for teletherapy, remote afterloader units, and gamma stereotactic radiosurgery.

(*i*) The licensee shall require the authorized user of a sealed source in a teletherapy unit to be a physician who:

(*I*) is certified in:

(-a-) therapeutic radiology, radiation oncology, or radiology by the ABR;

(-b-) therapeutic radiology, radiation oncology, or radiology by the AOBR;

(-c-) radiology with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(-d-) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(*II*) is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

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(-a-) 200 hours of classroom and laboratory training that includes:

(-1-) radiation physics and instrumentation;

(-2-) radiation protection;

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

(-4-) radiation biology; and

(-b-) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(-1-) review of the full calibration measurements and periodic spot checks;

(-2-) preparing treatment plans and calculating treatment times;

(-3-) using administrative controls to prevent misadministration;

(-4-) implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(-5-) checking and using survey meters; and

(-c-) three years of supervised clinical experience that includes one year in a formal training program accredited by the ACGME or the COPT-AOA and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(-1-) examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment; and any limitations or contraindications;

(-2-) selecting the proper dose and how it is to be administered;

(-3-) calculating the therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(-4-) post-administration follow-up and review of case histories.

(*ii*) Training in all the topics identified in clause (*i*)(*II*)(-a-) of this subparagraph shall be accredited by the ACGME or the COPT-AOA. The clinical experience described in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph shall be supervised by a physician licensed for teletherapy procedures. The experience in clause (*i*)(*II*)(-b-) and (-c-) of this subparagraph may be obtained concurrently.

(H) Training for experienced authorized users. Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a NRC or agreement state license issued before September 1, 1993, and those issued by the agency before October 1, 1995, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements in this paragraph.

(I) Recentness of training. The training and experience specified in this paragraph for medical use shall have been obtained within the five 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.

(2) Records/documents for agency inspection. Each licensee shall make the following records/documents available to the agency for inspection, upon reasonable notice.

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Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
(g)(3)	Qualifications and dates of service for temporary RSO	3 years
(n)	Copy of the current radioactive material license	Until termination of the radioactive material license
	Current operating, safety, and emergency procedures	Until termination of the radioactive material license
	Current applicable sections of this chapter as listed in the radioactive material license	Until termination of the radioactive material license
	Records of receipt, transfer, and disposal of radioactive material	Until disposal is authorized by the agency
	Records of leak tests for specific devices and sealed sources	3 years
	Shipping papers	3 years
(p)(3)	Written directives	3 years
(q)(4)	Calibration of instruments (dose calibrators)	3 years
(r)(5)	Determination of dosage of radioactive material for medical use	3 years

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
(s)(5)	Calibration/reference source inventory	3 years
(t)(2)	Sealed source/brachytherapy inventory	3 years
(v)(3)	Surveys for ambient radiation exposure rate	Duration of use of units
(w)(3)	Patient release	3 years after date of release
(x)(2)	Decay in storage/disposal	3 years
(z)(3)(C)	Molybdenum-99 concentrations	3 years
(aa)(2)(B)	Safety instructions - unsealed radioactive materials therapy	3 years
(bb)(2)(C)	Surveys - after sealed source implant and removal	3 years
(bb)(3)(C)	Brachytherapy sealed source inventory	3 years
(bb)(4)(B)	Safety instructions - manual brachytherapy	3 years
(bb)(6)(D)	Calibration measurements of brachytherapy sealed sources	3 years
(dd)(2)(B)	Surveys - patients treated with remote afterloaders	Duration of use of units
(dd)(3)(D)	Installation, maintenance and repair of remote afterloaders, teletherapy units and gamma stereotactic radiotherapy units	3 years

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
(dd)(4)(H)	Safety instructions and drills - remote afterloader, teletherapy, gamma stereotactic units	3 years
(dd)(6)(C)	Calibration, intercomparison, comparison of dosimetry equipment	3 years
(dd)(7)(G)	Calibration/teletherapy units	3 years
(dd)(8)(I)	Calibration/remote afterloader units	3 years
(dd)(9)(G)	Calibration/gamma stereotactic radiotherapy units	3 years
(dd)(10)(F)	Periodic spot checks for teletherapy units	3 years
(dd)(11)(F)	Periodic spot checks for remote afterloader units	3 years
(dd)(12)(H)	Periodic spot checks for gamma stereotactic radiotherapy units	3 years
(dd)(13)(E)	Periodic spot checks for mobile remote afterloader units	3 years
(dd)(14)(C)	Surveys - gamma stereotactic radiosurgery units	Duration of use of units
(dd)(15)(C)	5 yr inspection for teletherapy gamma stereotactic radiotherapy	Duration of use of units
(ee)(7),(16)	Medical events, dose to embryo/ fetus or nursing child	3 years