25 TEXAS ADMINISTRATIVE CODE

§289.256

Medical and Veterinary Use of Radioactive Material

Texas Regulation for Control of Radiation

(Effective January 4, 2022)

(Shaded text is added text or significant changes to Sept 2018 rule. Please note, you may have to adjust your printer's contrast setting for best printing results.)

Page

Page

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER F MEDICAL AND VETERAINRY USE OF RADIOACTIVE MATERIAL

§289.256. Medical and Veterinary Use of Radioactive Material.

(a) Purpose.

(1) 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 manufacture, produce, 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.

(2) A person who manufactures, produces, receives, possesses, uses, transfers, owns, or acquires radioactive material prior to receiving a license is subject to the requirements of this chapter.

(3) A specific license is not needed for a person who:

(A) receives, possesses, uses, or transfers radioactive material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in subsection (s) of this section, unless prohibited by license condition; or

(B) prepares unsealed radioactive material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in subsection (s) of this section, unless prohibited by license condition.

(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 Materials), §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 comply with the requirements of this section except for subsections (d), (dd) and (uuu) of this section.

(3) An entity that is a "covered entity" as that term is defined in HIPAA (the

Health Insurance Portability and Accountability Act of 1996, Title 45, Code of Federal Regulations (CFR), Parts 160 and 164) may be subject to privacy standards governing how information that identifies a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department making a referral of a potential violation to the United States Department of Health and Human Services.

(4) In accordance with the requirements of the Texas Medical Board, Title 22, Texas Administrative Code (TAC), Chapter 160, medical licensees must use the services of a licensed medical physicist for activities falling within the medical physicist scope of practice as identified in 22 TAC §160.17 unless exempted under 22 TAC §160.5.

(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) Associate radiation safety officer (ARSO)--An individual who:

(A) meets the requirements in subsections (h) and (m) of this section; and

(B) is currently identified as an ARSO for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer (RSO) on:

(i) a specific medical use license issued by the department, the United States Nuclear Regulatory Commission (NRC), or an agreement state; or

(ii) a medical use permit issued by an NRC master material licensee.

(4) Authorized medical physicist--An individual who meets the following:

(A) the requirements in subsections (j) and (m) of this section; or

(B) is identified as an authorized medical physicist or teletherapy physicist on one of the following:

(i) a specific medical use license issued by the department, the NRC, or an agreement state;

(ii) a medical use permit issued by an NRC master material licensee;

(iii) a permit issued by an NRC, or agreement state broad scope medical use licensee; or

(iv) a permit issued by an NRC master material license broad scope medical use permittee; and

(C) holds a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in therapeutic radiological physics for uses in subsections (rr) and (ddd) of this section.

(5) Authorized nuclear pharmacist--A pharmacist who meets the following:

(A) the requirements in subsections (k) and (m) of this section; or

(B) is identified as an authorized nuclear pharmacist on one of the following:

(i) a specific license issued by the department, the NRC, or an agreement state that authorizes medical use or the practice of nuclear pharmacy;

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

(iii) a permit issued by the department, the NRC, or an agreement state licensee of broad scope that authorizes medical use or the practice of nuclear pharmacy; or

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

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

(D) is designated as an authorized nuclear pharmacist in accordance with §289.252(r) of this title; and

(E) holds a current Texas license under the Texas Pharmacy Act, Texas Occupations Code, Chapters 551 - 566, 568, and 569, as amended, and who is certified as an authorized nuclear pharmacist by the Texas State Board of Pharmacy.

(6) Authorized user--An authorized user is defined as follows:

(A) for human use, a physician licensed by the Texas Medical Board; or a dentist licensed by the Texas State Board of Dental Examiners; or a podiatrist licensed by the Texas State Board of Podiatric Medicine who:

(i) meets the requirements in subsection (m) and subsections (gg), (jj), (nn), (oo), (pp), (qq), (zz), (aaa), (ccc) or (ttt) of this section; or

(ii) is identified as an authorized user on any of the following:

(I) an agency, NRC, or agreement state license that authorizes the medical use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee of broad scope issued by the department, the NRC, or an agreement state authorizing the medical use of radioactive material; or

(IV) a permit issued by an NRC master material licensee of broad scope that is authorized to permit the medical use of radioactive material.

(B) for veterinary use, an individual who is, a veterinarian licensed by the Texas State Board of Veterinary Medical Examiners; and

(i) is certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine; or

(ii) has received training in accordance with subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc), and (ttt) of this section as applicable; or

(iii) is identified as an authorized user on any of the following:

(I) an agency, NRC, or agreement state license that authorizes the veterinary use of radioactive material;

(II) a permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;

(III) a permit issued by a specific licensee of broad scope issued by the department, the NRC, or an agreement state authorizing the medical or veterinary use of radioactive material; or

(IV) a permit issued by an NRC master material licensee of broad scope that authorizes the medical use of radioactive material.

(7) 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.

(8) 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.

(9) 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.

(10) 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 (FDA) to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(11) 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.

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

(13) 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.

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

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

(16) 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.

(17) 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.

(18) Mobile nuclear medicine service--A licensed service authorized to transport radioactive material to, and medical use of the material at, the client's address. Services transporting calibration sources only are not considered mobile nuclear medicine licensees.

(19) Ophthalmic physicist--An individual who:

(A) meets the requirements in subsections (m) and (xx)(1)(B) of this section; and

(B) is identified as an ophthalmic physicist on:

(i) a specific medical use license issued by the department, the NRC, or an agreement state;

(ii) a permit issued by an agency, NRC, or agreement state broad scope medical use licensee;

(iii) a medical use permit issued by an NRC master material licensee; or

(iv) a permit issued by an NRC master material licensee broad scope medical use permittee.

(20) 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.

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

(22) Patient intervention--Actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(23) 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.

(24) Preceptor--An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, an RSO, or an ARSO.

(25) Prescribed dosage--The specified activity or range of activity of unsealed radioactive material as documented in a written directive or in accordance with the directions of the authorized user for procedures in subsections (ff) and (hh) of this section.

(26) 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.

(27) 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.

(28) Radiation safety officer (RSO)--For purposes of this section, an individual who:

(A) meets the requirements in subsections (h) and (m) of this section; or

(B) is identified as an RSO on one of the following:

(i) a specific license issued by the department, the NRC, or an agreement state that authorizes the medical or veterinary use of radioactive material; or

(ii) a permit issued by an NRC master material licensee that authorizes the medical or veterinary use of radioactive material.

(29) 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.

(30) 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.

(31) Technologist-- A person (nuclear medicine technologist) skilled in the performance of nuclear medicine procedures under the supervision of a physician.

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

(33) 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.

(34) 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.

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

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

(A) uptake, dilution, and excretion studies in subsection (ff) of this section;

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

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

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

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

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

(G) other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use in subsection (q) of this section.

(37) 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.

(38) 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.

(39) 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 (t) of this section.

(d) Provisions for research involving human subjects.

(1) A licensee may conduct research involving human subjects only if it uses the radioactive materials specified on its license for the uses 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, 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) Before 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) review and approval of the research 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 the effective date of this rule, 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 subsections (ggg) and (mmm) - (ooo) 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 (n) - (q) of this section, as applicable, a license will be issued if the department determines that:

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

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

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

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

(iv) waste disposal procedures; and

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

(C) qualifications of the following:

(i) RSO in accordance with subsection (c)(28) of this section;

(ii) authorized user(s) in accordance with subsection (c)(6) of this section as applicable to the use(s) being requested;

(iii) authorized medical physicist in accordance with subsection (c)(4) of this section, if applicable;

(iv) authorized nuclear pharmacist in accordance with subsection (c)(5) of this section, if applicable;

(v) ophthalmic physicist in accordance with subsection (c)(19), if applicable;

(vi) Radiation Safety Committee (RSC), in accordance with subsection (i) of this section, if applicable; and

(vii) ARSO in accordance with subsection (c)(3) of this section, if applicable; and

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

(g) Authority and responsibilities for the radiation protection program

(1) In addition to the radiation protection program requirements of §289.202(e) of this title, a licensee's management shall approve in writing:

(A) requests for a license application, renewal, or amendment before submittal to the department; and

(B) any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

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

(3) Every licensee shall establish in writing the authority, duties, and responsibilities of the RSO and ensure that the RSO is provided sufficient authority, organizational freedom, time, resources, and management prerogative to perform the following duties:

(A) 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;

(B) 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;

(C) 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;

(D) investigate and cause a report to be submitted to the department 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;

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

(F) have a thorough knowledge of management policies and administrative

procedures of the licensee;

(G) identify radiation safety problems;

(H) assume control and initiate, recommend, or provide corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(I) verify implementation of corrective actions;

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

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

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

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

(N) serve as the primary contact with the department.

(4) The RSO shall ensure that the duties listed in paragraph (3)(A) - (N) of this subsection are performed.

(5) The RSO shall be on site periodically commensurate with the scope of licensed activities to satisfy the requirements of paragraphs (3) and (4) of this subsection.

(6) The RSO, or staff designated by the RSO, shall be capable of physically arriving at the licensee's authorized use site(s) within a reasonable time of being notified of an emergency situation or unsafe condition.

(7) For up to 60 days each calendar year, a licensee may permit an authorized user or an individual qualified to be an RSO, under subsections (h) and (m) of this section, to function as a temporary RSO and to perform the duties of an RSO in accordance with paragraph (3) of this subsection, provided the licensee takes the actions required in paragraphs (2), (3), and (9) of this subsection, and notifies the department in accordance with subsection (r)(5) of this section. Records of qualifications and dates of service shall be maintained in accordance with subsection (xxx) of this section for inspection by the department.

(8) A licensee may simultaneously appoint more than one temporary RSO in accordance with paragraph (7) of this subsection, if needed to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different types of uses of radioactive material permitted by the license.

(9) The licensee shall maintain records, in accordance with subsection (xxx) of this section, as follows.

(A) A licensee shall retain a record of actions taken by the licensee's management in accordance with paragraph (1) of this subsection. The record must include a summary of the actions taken and a signature of licensee management.

(B) The authority, duties, and responsibilities of the RSO as required by paragraph (3) of this subsection, and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by paragraph (2) of this subsection. The records must include the signature of the RSO and licensee management.

(C) A copy of the written document appointing the ARSO, for each ARSO appointed under paragraph (2) of this subsection. The record must include the signature of licensee management.

(h) Training for an RSO and ARSO. Except as provided in subsection (l) of this section, the licensee shall require the individual fulfilling the responsibilities of an RSO or an individual assigned duties and tasks as an ARSO in accordance with subsection (g) of this section for licenses for medical or veterinary use of radioactive material to be an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (4) of this subsection. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page:

(A) to have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

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

(B) to have its certification process recognized, a specialty board shall require all candidates for certification to:

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

(ii) have two years of full-time practical training and/or supervised

experience in medical physics as follows:

(I) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the department, the NRC, or an agreement state; or

(II) in clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in subsections (l), (jj), or (nn) of this section; and

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

(2) has completed all of the following:

(A) a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory 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, or agreement state license or on a permit issued by an NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material. An ARSO may provide supervision for those areas for which the ARSO is authorized on an agency, NRC, or an agreement state license or a permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

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

(II) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instrument 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;

(VI) using emergency procedures to control radioactive material; and

(VII) disposing of radioactive material; and

(B) has obtained written attestation, signed by a preceptor RSO or ARSO who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as an RSO or an ARSO, and the written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (2)(A) and (4) of this subsection, and is able to independently fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use license; or

(3) meets one of the following:

(A) is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state in accordance with subsection (j)(1) of this section and has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO or an ARSO and who meets the requirements in paragraph (4) of this subsection;

(B) is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an agency, NRC, or another agreement state's license, a permit issued by a NRC master material licensee, a permit issued by the department, the NRC, or another agreement state licensee of broad scope, or a permit issued by a NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee is seeking the approval of the individual as the RSO or ARSO, and who meets the requirements in paragraph (4) of this subsection; or

(C) has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the RSO and the authorized user on the same new medical use license or new medical use permit issued by a NRC master material license. The individual must also meet the requirements in paragraph (4) of this subsection and

(4) has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval, and this training requirement may be satisfied by completing training that is supervised by an RSO, an ARSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(i) Radiation safety committee (RSC). Licensees of broad scope and licensees who are authorized for two or more different types of uses of radioactive material in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units under subsection (ddd) 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 department:

(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 in accordance with subsections (kk), (rr), and (ddd) of this section, or two or more types of units in accordance with subsection (ddd) of this section shall be composed of the following individuals as approved by the department:

(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 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 of broad scope, the duties and responsibilities of the RSC include 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 before implementation.

(4) Records documenting the RSC meetings shall be made and maintained for inspection by the department in accordance with subsection (xxx) of this section. The record shall include the date, names of individuals in attendance, minutes of the meeting, and any actions taken.

(j) Training for an authorized medical physicist. Except as provided in subsection (l) of this section, the licensee shall require the authorized medical physicist to be:

(1) an individual who is certified by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (3) of this subsection. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to meet the following:

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

(B) complete two years of full-time practical training and/or supervised experience in medical physics as follows:

(i) under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized by the department, the NRC, or an agreement state; or

(ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in subsections (l), (zz) or (ttt) of this section; and

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

(2) an individual who:

(A) holds a post graduate degree and experience to include:

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

(ii) completion of one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization, and this training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and shall include:

(I) performing sealed source leak tests and inventories;

(II) performing decay corrections;

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

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

(B) has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (2)(A) and (3) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status, and the written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

(k) Training for an authorized nuclear pharmacist. Except as provided in subsection (l) of this section, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) is certified by a specialty board whose certification process has been recognized by the department, the NRC or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(B) hold a current, active license to practice pharmacy in the State of Texas;

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

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

(2) has completed:

(A) a 700-hour structured educational program, including both:

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

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) supervised practical experience in a nuclear pharmacy involving the following:

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

(II) using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate,

instruments used to measure alpha- or beta-emitting radionuclides;

(III) calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) using administrative controls to avoid medical events in the administration of radioactive material; and

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

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

(l) Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

(1) An individual identified on an agency, NRC, or an agreement state license or a permit issued by the department, the NRC, or an agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope as an RSO, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of subsections (h), (j), and (k) of this section, respectively, except the RSO and authorized medical physicists identified in this paragraph must meet the training requirements in subsections (h)(4) or (j)(3) of this section, as appropriate, for any material or uses for which they were not authorized before this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of subsection (h) of this section to be identified as an RSO or as an ARSO on an agency, NRC, or agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

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

(4) An RSO, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subsections (h), (j) or (k) of this section, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(5) An individual identified as a physician, dentist, podiatrist or veterinarian authorized for the medical or veterinary use of radioactive material.

(A) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, or an agreement state, a permit issued by an NRC master material licensee, a permit issued by the department, the NRC, or an agreement state broad scope licensee, or a permit issued by an NRC master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subsections (gg) through (ttt) of this section.

(B) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the department, the NRC, or an agreement state, a permit issued by an NRC master material licensee, a permit issued by the department, the NRC, or an agreement state broad scope licensee, or a permit issued by an NRC master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of subsections (gg) through (ttt) of this section for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

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

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

(iii) For uses authorized under subsections (rr) or (ddd) of this section, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

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

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

(6) Individuals who need not comply with training requirements in this subsection may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency, NRC, or agreement state license for the same uses for which these individuals are authorized.

(m) Recentness of training. The training and experience specified in subsections (h), (j), and (gg) - (ttt) of this section for medical and veterinary use shall have been obtained within the seven 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.

(n) 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 (ff), (hh), (kk), (rr), (bbb) and (ddd) of this section will be issued if the department approves the following documentation submitted by the applicant:

(1) that the physician(s) or veterinarian(s) designated on the application as the authorized user(s) is qualified in accordance with subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc) and (ttt) 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) that an RSC has been established in accordance with subsection (i)(2) of this section, if applicable.

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

(1) that the review of authorized user qualifications by the RSC is in accordance with subsections (gg), (jj), (nn) - (qq), (zz), (aaa), (ccc) and (ttt) 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) that the full-time RSO meets the requirements of subsection (h) of this section; and

(7) that an RSC has been established in accordance with subsection (i)(1) of this section.

(p) License for the use of remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units. In addition to the requirements of subsection (f) of this section, a license for the use of remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units will be issued if the department 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 (ttt) 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) of the radioactive isotopes to be possessed;

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

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

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

(A) remote afterloader unit;

(B) teletherapy unit; or

(C) gamma stereotactic radiosurgery unit;

(8) that the authorized medical physicist designated on the application is qualified in accordance with subsection (j) of this section;

(9) of the safety procedures and instructions as required by subsection (ggg) of this section;

(10) of the spot check procedures as required by subsections (mmm) - (ooo) of this section, as applicable; and

(11) that an RSC has been established in accordance with subsection (i)(1) or (2) of this section if applicable.

(q) License for other medical or veterinary uses of radioactive material or a radiation source approved for medical or veterinary use that is not specifically addressed in this section. In addition to the requirements of subsection (f) of this section, a licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in this section if:

(1) the department approves the following documentation submitted by the applicant:

(A) any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, requirements in this section;

(B) identification of and commitment to follow the applicable radiation safety program requirements in this section that are appropriate for the specific medical use;

(C) any additional specific information on:

(i) radiation safety precautions and instructions;

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

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

(D) any other information requested by the department in its review of the application; and

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

(r) License amendments and notifications.

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

(2) A licensee shall apply for and shall receive a license amendment before the following:

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

(B) permitting anyone to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist, under the license except an individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist:

(i) on an agency, NRC or agreement state license or other equivalent permit or license recognized by the department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(ii) on a permit issued by an agency, NRC or agreement state specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(iii) on a permit issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

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

(C) changing RSOs, except as provided in subsection (g)(7) 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 in which radioactive material is used or stored and are identified in the application or on the license, including areas used in accordance with subsection (ff) or (hh) of this section if the change includes

addition or relocation of either an area where positron emission tomography (PET) radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area, and other areas of use where radioactive material is used only in accordance with either subsection (ff) or (hh) of this section are exempt;

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

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

(H) before permitting anyone to work as an ARSO, or before the RSO assigns duties and tasks to an ARSO that differ from those for which this individual is authorized on the license; and

(I) before receiving a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(3) A licensee possessing a Type A specific license of broad scope for medical use, issued under §289.252(h)(2) of this title, is exempt from:

(A) the provisions of subsection (q)(1) of this section regarding the need to file an amendment to the license for medical use of radioactive material;

(B) the provisions of paragraph (2)(B) of this subsection;

(C) the provisions of paragraph (2)(E) of this subsection regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(D) the provisions of paragraph (4) of this subsection;

(E) the provisions of paragraph (5)(A) of this subsection for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist;

(F) the provisions of paragraph (5)(C) of this subsection; and

(G) the provisions of subsection (u)(1) of this section.

(4) A licensee shall notify the department in the form of a license amendment request, no later than 30 days after the date that the licensee permits an individual to work under the provisions of §289.256(r) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist providing that the individual is authorized on a license for the same use. A licensee includes with the notification documentation:

(A) a copy of the department, NRC, or agreement state license;

(B) the permit issued by an NRC master material licensee;

(C) the permit issued by the department, the NRC, or an agreement state licensee of broad scope; or

(D) the permit issued by an NRC master material license broad scope permittee.

(5) A licensee shall notify the department in the form of a license amendment request no later than 30 days after:

(A) an authorized user, an authorized nuclear pharmacist, an RSO, an ARSO, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(B) the licensee permits an individual qualified to be an RSO under subsections (h) and (m) of this section to function as a temporary RSO and to perform the functions of an RSO in accordance with subsection (g)(6) of this section;

(C) the licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either subsection (ff) or (hh) of this section, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(D) the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in paragraph (1) of this subsection. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(s) 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, written

directive procedures, 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 nuclear pharmacist or 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 or authorized nuclear pharmacist 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 in accordance with paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

(4) Only an authorized user may authorize the medical use of radioactive material.

(t) Written directives.

(1) A written directive shall be dated and signed by an authorized user before any administration of sodium iodide I-131 greater than 30 microcuries (μCi) (1.11 megabequerels (MBq)), administration of any therapeutic dosage of unsealed radioactive material, or administration of any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented in writing as soon as possible in the patient's record. A written directive shall be prepared and signed by the authorized user within 48 hours of the oral directive.

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

(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, the dosage, and the route of administration.

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

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

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

(F) For permanent implant brachytherapy:

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

(ii) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

(G) For all other brachytherapy, including low, medium, and pulsed rate afterloaders:

(i) before implantation: the treatment site, the radionuclide, and the dose;

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

(3) A written revision to an existing written directive.

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

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

(4) The licensee shall retain the written directive in accordance with subsection (xxx) of this section for inspection by the department.

(5) 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 provide high confidence 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) verifying the identity of the patient or human research subject;

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

(iii) checking both manual and computer-generated dose calculations; and

(iv) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by subsections (q) and (ddd) of this section;

(v) determining if a medical event, as defined in subsection (uuu) of this section, has occurred; and

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

(C) A licensee shall maintain a copy of the procedures required by subparagraph (A) of this paragraph in accordance with subsection (xxx) of this section.

(u) Suppliers for sealed sources or devices for medical use. A licensee may only use the following for medical use:

(1) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under §289.252(o) of this title or equivalent requirements of the NRC or an agreement state;

(2) sealed sources or devices non-commercially transferred from an NRC or agreement state medical use licensee; or

(3) teletherapy sources manufactured and distributed in accordance with a license issued by the department, the NRC, or an agreement state.

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

(1) For direct measurements performed in accordance with subsection (x) 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 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 before 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 (xxx) of this section. The record shall include the following:

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

(B) complete date of the calibration including the month, day and year;

(C) results of the calibration; and

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

(w) Calibration of survey instruments. A licensee shall calibrate the survey instruments used to show compliance with this subsection and with §289.202 of this title before first use, annually, and following a repair that affects the calibration. A licensee shall:

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

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

(3) conspicuously note on the instrument the complete date of the calibration including the month, day, and year;

(4) not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent; and

(5) maintain a record of each survey instrument calibration in accordance with subsection (xxx) of this section.

(x) Determination of dosages of unsealed radioactive material for medical use.

(1) Before medical use, the licensee shall determine and record the activity of each dosage.

(2) For a unit dosage, this determination shall be made by:

(A) direct measurement of radioactivity; or

(B) 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 or agreement state license;

(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; or

(iii) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements.

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

(A) direct measurement of radioactivity;

(B) combination of measurement of radioactivity and mathematical calculations; or

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

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

(ii) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements.

(4) 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 percent.

(5) A licensee restricted to only unit doses prepared in accordance with §289.252(r) of this title need not comply with paragraph (2) 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.

(6) A licensee shall maintain a record of the dosage determination required by this subsection in accordance with subsection (xxx) of this section for inspection by the department. The record shall contain the following:

(A) 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.

(y) Authorization for calibration, transmission, and reference sources.

(1) Any licensee authorized by subsections (n), (o), (p) or (q) of this section for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

(A) sealed sources, not exceeding 30 millicuries (mCi) (1.11 gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under §289.252(o) of this title or equivalent NRC or agreement state regulations;

(B) sealed sources, not exceeding 30 millicuries (mCi) (1.11 gigabecquerel (GBq)) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under §289.252(o) of this title or equivalent NRC or agreement state regulations, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(C) any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(D) 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 §289.202(ggg)(3) of this title; and

(E) technetium-99m in amounts as needed.

(2) Radioactive material in sealed sources authorized by this subsection shall not be:

(A) used for medical use as defined in subsection (c) of this section except in accordance with the requirements in subsection (bbb) of this section; or

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

(3) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (1) or (2) of this subsection need not list these sources on a specific medical use license.

(z) 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 and reporting requirements in §289.202(bbb) of this title; and

(2) conduct a physical inventory at intervals not to exceed six months to account for all sealed sources in its possession. Records of the inventory shall be made and maintained for inspection by the department in accordance with subsection (xxx) of this section and shall include the following:

(A) model number of each source and serial number if one has been assigned;

(B) identity of each source and its nominal activity;

(C) location of each source;

(D) date of the inventory; and

(E) identification of the individual who performed the inventory.

(aa) 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.

(bb) Surveys for ambient radiation exposure rate.

(1) In addition to the requirements of §289.202(p) of this title and 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 (cc) 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 retained in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

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

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

(cc) 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 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 mrem (0.05 mSv) 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 nursing 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 for inspection by the department, a record in accordance with subsection (xxx) 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).

(dd) Mobile nuclear medicine service. A license for a mobile nuclear medicine service for medical or veterinary use of radioactive material will be issued if the department approves the documentation submitted by the applicant in accordance with the requirements of subsections (f) and (n) of this section. The clients of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by the mobile nuclear medicine service.

(1) A licensee providing mobile nuclear medicine service shall:

(A) obtain a letter signed by the management of each client for which

services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

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

(C) have at least one fixed facility where records may be maintained and radioactive material may be delivered by manufacturers or distributors each day before the mobile nuclear medicine licensee dispatching its vans to client sites;

(D) agree to have an authorized physician user directly supervise each technologist at a reasonable frequency;

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

(F) before leaving a client's address, survey all areas of use to ensure compliance with the requirements of §289.202 of this title.

(2) A mobile nuclear medicine service shall not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(3) A licensee providing mobile nuclear medicine services shall maintain records, for inspection by the department, in accordance with subsection (xxx) of this section including the letter required in paragraph (1)(A) of this subsection and the record of each survey required in paragraph (1)(F) of this subsection.

(ee) Decay-in-storage.

(1) The licensee may hold radioactive material with a physical half-life of less than or equal to 120 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 radiation labels on materials that are within containers and that will be handled as biomedical waste after it has been released from the licensee.

(2) The licensee shall retain a record of each disposal as required by paragraph (1) of this subsection in accordance with subsection (xxx) of this section for

inspection by the department. The record shall include the following:

(A) date of the disposal;

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

(C) background radiation level;

(D) radiation level measured at the surface of each waste container; and

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

(ff) Use of unsealed radioactive material for uptake, dilution, and excretion studies that do not require a written directive. Except for quantities that require a written directive in accordance with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for uptake, dilution, or excretion studies that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252(r) of this title or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(A)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician who is an authorized user in subparagraph (B) of this paragraph; or

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

(4) 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.

(gg) Training for uptake, dilution, and excretion studies. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (ff) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the department, the NRC or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board shall require all candidates for certification to:

(A) complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in paragraph (3)(A) of this subsection; and

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

(2) is an authorized user in accordance with subsections (jj) or (nn) of this section or equivalent NRC or agreement state requirements; or

(3) has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies.

(A) The training and experience shall include the following:

(i) classroom and laboratory training in the following areas:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user who meets the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements involving the following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages of radioactive drugs to patients or human research subjects; and

(B) has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraph (A) of this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under subsection (ff) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, or subsections (jj) or (nn) of this section, or equivalent NRC or agreement state requirements; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l), (gg), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph (A) of this paragraph.

(hh) Use of unsealed radioactive material for imaging and localization studies that do not require a written directive. Except for quantities that require a written directive in accordance with subsection (t) of this section, a licensee may use any unsealed radioactive material prepared for medical or veterinary use for imaging and localization studies that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252(r) of this title or equivalent NRC or agreement state requirements; or

(B) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(3)(A)(ii)(VII) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician who is an authorized user in subparagraph (B) of this paragraph; or

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

(4) 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.

(ii) Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

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

(A) more than 0.15 µCi of molybdenum-99 per mCi of technetium-99m (0.15 kilobecquerel (kBq) of molybdenum-99 per MBq of technetium-99m); or

(B) more than 0.02 µCi of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride) injection; or

(C) more than 0.2 µCi of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride) injection.

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

(3) The licensee who uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (1) of this subsection.

(4) If the licensee is required to measure the molybdenum-99 or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with subsection (www) of this section for inspection by the department. The record shall include the following:

(A) for each measured elution of technetium-99m:

(i) the ratio of the measures expressed as µCi of molybdenum-99 per mCi of technetium-99m (kBq of molybdenum-99 per MBq of technetium-99m);

(ii) time and date of the measurement; and

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

(B) for each measured elution of rubidium-82:

(i) the ratio of the measures expressed as µCi of strontium-82 per mCi of rubidium (kBq of strontium-82 per MBq of rubidium-82);

(ii) the ratio of the measures expressed as µCi of strontium-85 per mCi of rubidium (kBq of strontium-85 per MBq of rubidium-82);

(iii) time and date of the measurement; and

(iv) name of the individual who made the measurement.

(5) The licensee shall report any measurement that exceeds the limits in paragraph (1) of this subsection at the time of generator elution, in accordance with subsection (xxx) of this section.

(jj) Training for imaging and localization studies. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (hh) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the department, the NRC or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in paragraph (3) of this subsection; and

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

(2) is an authorized user in accordance with subsection (nn) of this section and meets the requirements of paragraph (3)(A)(ii)(VII) of this subsection or equivalent NRC or agreement state requirements; or

(3) has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for

imaging and localization studies.

(A) The training and experience shall include the following:

(i) classroom and laboratory training in the following areas:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience under the supervision of an authorized user who meets the requirements in subsection (l) of this section, this subsection, or paragraph (3)(A)(ii)(VII) of this section, and subsection (nn) of this section, or equivalent NRC or agreement state requirements. An authorized nuclear pharmacist who meets the requirements in subsections (k) or (l) of this section may provide the supervised work experience for subclause (VII) of this clause. Work experience must involve the following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages of radioactive drugs to patients or human research subjects; and

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

(B) has obtained written attestation that the individual has satisfactorily completed the requirements in this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses

authorized under subsections (ff) and (hh) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or paragraph (3)(A)(ii)(VII) of this subsection and subsection (nn) of this section or equivalent NRC or agreement state requirements; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l), or (jj), or (nn) of this section and paragraph (3)(A)(ii)(VII) of this subsection, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(kk) Use of unsealed radioactive material that requires a written directive. A licensee may use any unsealed radioactive material identified in subsection (nn)(2)(A)(ii)(VI) of this section prepared for medical use that requires a written directive that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252(r) of this title or equivalent NRC or agreement state requirements;

(B) a PET radioactive drug producer licensed in accordance with §289.252(kk) of this title or equivalent NRC or agreement state requirements; or

(2) excluding production of PET radionuclides, prepared by:

(A) an authorized nuclear pharmacist; or

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) of this section; or

(C) an individual under the supervision, as specified in subsection (s) of this section, of the authorized nuclear pharmacist in subparagraph (A) of this paragraph, or the physician who is an authorized user in subparagraph (B) of this paragraph; or

(3) is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with an IND protocol accepted by the FDA; or

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

(ll) Safety instruction to personnel.

(1) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human or animal research subjects who cannot be released in accordance with subsection (cc) of this section. The instruction shall be appropriate to the personnel's assigned duties and include the following:

(A) patient or human or animal research subject control; and

(B) 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 an authorized user if the patient or the human or animal research subject has a medical emergency or dies.

(2) The licensee shall maintain a record for inspection by the department, in accordance with subsection (xxx) of this section, of individuals receiving instruction. The record shall include the following:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(mm) Safety precautions. For each human patient or human research subject who cannot be released in accordance with subsection (cc) of this section, the licensee shall do the following:

(1) provide a private room with a private sanitary facility; or

(2) provide a room with a private sanitary facility with another individual who also has received therapy with an unsealed radioactive material and who also cannot be released in accordance with subsection (cc) of this section;

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

(4) either monitor material and items removed from the patient's or the 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; and

(5) notify the RSO, or his or her designee, and the authorized user immediately if the patient or research subject has a medical emergency or dies.

(nn) Training for use of unsealed radioactive material that requires a written directive. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized in subsection (kk) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements in paragraph (2)(A)(ii)(VI) of this subsection. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

(A) successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in paragraph (2)(A)(i) – (2)(A)(ii)(V) of this subsection. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

(2) has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive.

(A) The training and experience shall include the following.

(i) classroom and laboratory training in the following areas:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements of this paragraph shall also have experience in administering dosages in the same dosage category or categories (i.e. subclause (VI) of this clause) as the individual requesting authorized user status. The work experience shall involve the following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages of radioactive drugs to patients or human research subjects from the three categories in the following items. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under subsection (q) of this section. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(-a-) oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required;

(-b-) oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131 (experience with at least three cases in this item also satisfies the requirement of item (-a-) of this subclause); and

(-c-) parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 kiloelectron volts (keV) for which a written directive is required; and

(B) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (2)(A) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under subsection (kk) of this section for which the individual is requesting authorized user status. The attestation must be obtained

from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or equivalent NRC or agreement state requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l) or (nn) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph .

(oo) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements of paragraph (3)(A) of this subsection and whose certification has been recognized by the department, the NRC, or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

(2) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section, or subsection (pp) of this section, or equivalent NRC or agreement state requirements; or

(3) has successfully completed 80 hours of classroom and laboratory training and work experience applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(A) The training and experience shall include the following.

(i) classroom and laboratory training shall include the following:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section, or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section. The work experience shall involve the following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 33mCi (1.22 GBq) of sodium iodide I-131; and

(B) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (3)(A) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I–131 for medical uses authorized under subsection (kk) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, subsection (nn) or subsection (pp) of this section or equivalent NRC or agreement state requirements and has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-) of this section; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in

subsections (l), (nn), (oo) or (pp) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-a-) or (-b-), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(pp) Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq). Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi (1.22 GBq) to be a physician who:

(1) is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (3)(A) of this subsection and whose certification has been recognized by the department, the NRC, or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

(2) is an authorized user in accordance with subsection (nn) of this section or equivalent NRC or agreement state requirements for uses listed in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section; or

(3) has training and experience including, successful completion of 80 hours of classroom and laboratory training applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(A) The training and experience shall include the following.

(i) classroom and laboratory training shall include the following:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, subsections (nn) or (pp) of this section or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements of subsection (nn)(2) of this section, shall also have experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section. The work experience shall involve the

following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131; and

(B) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (3)(A) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I–131 for medical uses authorized under subsection (kk) of this section. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements in subsections (l) or (nn) of this section, this subsection, or equivalent NRC or agreement state requirements, and has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l), (nn), or (pp) of this section, or equivalent NRC, or agreement state requirements, has experience in administering dosages as specified in subsection (nn)(2)(A)(ii)(VI)(-b-) of this section, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(qq) Training for the parenteral administration of unsealed radioactive material requiring a written directive.

(1) Except as provided in subsection (l) of this section, the licensee shall require an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive to be a physician who:

(A) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section or equivalent NRC or agreement state requirements; or

(B) is an authorized user under subsections (zz) or (ttt) of this section or equivalent NRC or agreement state requirements and who meets the requirements of paragraph (2) of this subsection; or

(C) is certified by a medical specialty board whose certification process has been recognized by the department, the NRC, or an agreement state in accordance with subsections (zz) or (ttt) of this section, and who meets the requirements of paragraph (2) of this subsection.

(2) The physician must also meet the following requirements:

(A) has successfully completed 80 hours of classroom and laboratory training applicable to parenteral administrations listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section.

(B) has the training and experience that shall include the following:

(i) classroom and laboratory training shall include the following:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) chemistry of radioactive material for medical use; and

(V) radiation biology; and

(ii) work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection or subsection (nn) of this section or equivalent NRC or agreement state requirements in the parenteral administration listed in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section. A supervising authorized user who meets the requirements of subsection (nn) of this section, this subsection, or equivalent NRC or agreement state requirements shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience shall involve the following:

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

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

(III) calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(VI) administering dosages to patients or human research subjects that include at least three cases involving the parenteral administration specified in subsection (nn)(2)(A)(ii)(VI)(-c-) of this section; and

(C) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraph (2)(A) and (B) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements of subsection (l) of this section, subsection (nn) of this section, or this subsection, or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in subsection (nn) of this section, this section, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or, and shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsections (l), (nn) or (qq) of this section, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in this paragraph.

(rr) Use of sealed sources for manual brachytherapy. The licensee shall use only brachytherapy sources as follows:

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

(2) in research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

(ss) Surveys after sealed source implants and removal.

(1) 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.

(2) Immediately after removing the last temporary implant sealed source from a patient or a human or animal research subject, the licensee shall perform 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.

(3) A record of each survey shall be retained, for inspection by the department, in accordance with subsection (xxx) of this section. The record shall include the following:

(A) date 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.

(tt) Brachytherapy sealed sources accountability.

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

(2) 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.

(3) The licensee shall maintain a record of the brachytherapy sealed source accountability in accordance with subsection (xxx) of this section for inspection by the department.

(A) When removing temporary implants from storage, the licensee shall

record the number and activity of sources, time and date the sources were removed, the name of the individual who removed the sources, and the location of use. When temporary implants are returned to storage, record the number and activity of sources, the time and date, and the name of the individual who returned them.

(B) When removing permanent implants from storage, the licensee shall record the number and activity of sources, date, the name of the individual who removed the sources, and the number and activity of sources permanently implanted in the patient or human research subject. Record the number and activity of sources not implanted and returned to storage, the date, and the name of the individual who returned them to storage.

(uu) 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 receiving brachytherapy and who cannot be released in accordance with subsection (cc) of this section or animals that are confined.

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

(A) size and appearance of brachytherapy sources;

(B) safe handling and shielding instructions;

(C) patient or human research subject control;

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

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

(2) A licensee shall maintain a record, for inspection by the department, in accordance with subsection (xxx) of this section, of individuals receiving instruction. The record shall include the following:

(A) list of the topics covered;

(B) date of the instruction or training;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

(vv) Safety precautions for the use of brachytherapy.

(1) For each patient or human research subject who is receiving brachytherapy and cannot be released in accordance with subsection (cc) of this section the licensee shall:

(A) provide a private room with a private sanitary facility;

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

(C) have available near each treatment room applicable 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.

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

(ww) Calibration measurements of brachytherapy sealed sources.

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

(A) determine the sealed source output or activity using a dosimetry system that meets the requirements of subsection (iii)(1) of this section;

(B) determine sealed source positioning accuracy within applicators; and

(C) use published protocols accepted by nationally recognized bodies to meet the requirements of subparagraphs (A) and (B) of this paragraph.

(2) Instead of the licensee making its own measurements as required in paragraph (1) of this subsection, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (1) of this subsection.

(3) The licensee shall mathematically correct the outputs or activities determined in paragraph (1) of this subsection for physical decay at intervals consistent with one percent physical decay.

(4) The licensee shall retain a record of each calibration in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) complete date of the calibration including the month, day, and year;

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

(C) sealed source output or activity;

(D) sealed source positioning accuracy within applicators; and

(E) name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

(xx) Strontium-90 sources for ophthalmic treatments.

(1) A licensee who uses strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (2) of this subsection are performed by either:

(A) an authorized medical physicist; or

(B) an individual who:

(i) is identified as an ophthalmic physicist on a specific medical use license issued by the department, the NRC, or an agreement state; permit issued by the department, the NRC, or an agreement state broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material licensee broad scope medical use permittee; and

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

(iii) has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) has documented training in:

(I) the creation, modification, and completion of written directives;

(II) procedures for administrations requiring a written directive; and

(III) performing the calibration measurements of brachytherapy sources as detailed in subsection (ww) of this section.

(2) The individual who is identified in paragraph (1) of this subsection must:

(A) calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments, and the decay must be based on the activity determined under subsection (ww) of this section; and

(B) assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the

individual meeting the requirements in paragraph (1) of this subsection will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(3) A licensee shall maintain a record of the activity of a strontium-90 source in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date and initial activity of the source as determined under subsection (ww) of this section; and

(B) for each decay calculation, the date and the source activity as determined under this subsection.

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

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays; and

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

(zz) Training for use of manual brachytherapy sealed sources. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized in subsection (rr) of this section to be a physician who:

(1) is certified by a medical specialty board whose certification process has been recognized by the department, the NRC or an agreement state. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board shall require all candidates for certification to:

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

(B) pass an examination, administered by diplomates of the specialty board,

that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) has completed:

(A) a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources including the following:

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

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements at a medical facility authorized to use radioactive material under subsection (rr) of this section, involving the following:

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

(II) checking survey meters for proper operation;

(III) preparing, implanting, and removing brachytherapy sources;

(IV) maintaining running inventories of material on hand;

(V) using administrative controls to prevent a medical event involving the use of radioactive material; and

(VI) using emergency procedures to control radioactive material; and

(B) three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph (A)(ii) of this paragraph; and

(3) has obtained written attestation that the individual has satisfactorily

completed the requirements in paragraph (2) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under subsection (rr) of this section. The attestation must be obtained from either:

(A) a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements; or

(B) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (2) of this subsection.

(aaa) Training for ophthalmic use of strontium-90. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) is an authorized user under subsection (zz) of this section or equivalent NRC or agreement state requirements; or

(2) has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(A) The training shall include the following.

(i) classroom training shall include the following:

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) radiation biology; and

(ii) supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

(I) examination of each individual to be treated;

(II) calculation of the dose to be administered;

(III) administration of the dose; and

(IV) follow-up and review of each individual's case history; and

(3) has obtained written attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, subsection (zz) of this section or this subsection, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (2)(A) of this subsection and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

(bbb) Use of sealed sources and medical devices for diagnosis.

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

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

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

(4) The licensee shall ensure that installation or exchange of sealed source(s) in medical imaging equipment is performed only by the manufacturer or persons specifically authorized to perform these services by the department, the NRC, or another agreement state. The licensee shall maintain a record for each installation or exchange for inspection by the department in accordance with subsection (xxx) of this section. The record shall include the date, the installer’s radioactive material license number, and the regulatory agency that issued the license to the installer.

(ccc) Training for use of sealed sources for diagnosis. Except as provided in subsection (l) of this section, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized in accordance with subsection (bbb) of this section to be a physician, dentist, or podiatrist who:

(1) is certified by a specialty board whose certification process includes all of the requirements of paragraphs (3) and (4) of this subsection and whose certification has been recognized by the department, the NRC, or an agreement state. The names of board certifications that have been recognized by the department, the

NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

(2) is an authorized user for uses listed in subsection (hh) of this section or equivalent NRC or agreement state requirements; or

(3) has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:

(A) radiation physics and instrumentation;

(B) radiation protection;

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

(D) radiation biology; and

(4) has completed training in the use of the device for the uses requested.

(ddd) Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(1) The licensee shall only use sealed sources:

(A) as approved and as provided for in the Sealed Source and Device Registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(B) in research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active IDE application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

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

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

(B) in research in accordance with an active IDE application accepted by the FDA provided the requirements of subsection (u)(1) of this section are met.

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

(1) 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.

(2) The licensee shall maintain a record of the surveys in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date of the survey;

(B) results of the survey;

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

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

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

(1) Only a person specifically licensed by the department, the NRC, or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the 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).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, the NRC, or an agreement 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.

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

(4) 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 (xxx) of this section for inspection by the department. For each installation, maintenance, adjustment and repair, the record shall include the date, description of the service, and name(s) of the individual(s) who performed the work.

(ggg) Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(1) 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 authorized medical physicist 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; and

(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. The procedures 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 authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally;

(2) A copy of the procedures required by paragraph (1)(D) of this subsection must be physically located at the unit console.

(3) The licensee shall post instructions at the unit console to inform the operator of the following:

(A) the location of the procedures required by paragraph (1)(D) of this subsection; and

(B) the names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(4) Before the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit:

(A) a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(B) a licensee shall provide operational and safety instructions initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, to include:

(i) procedures identified in paragraph (1)(D) of this subsection; and

(ii) operating procedures for the unit.

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

(6) A licensee shall maintain records of the procedures required by paragraphs (1)(D) and (4)(B)(ii) of this subsection in accordance with subsection (xxx) of this section for inspection by the department.

(7) A licensee shall maintain records of individuals receiving instruction and participating in drills required by paragraphs (4) and (5) of this subsection in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) a list of the topics covered;

(B) date of the instruction or drill;

(C) name(s) of the attendee(s); and

(D) name(s) of the individual(s) who provided the instruction.

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

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

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

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

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

(C) 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;

(3) require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels;

(4) 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;

(5) 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;

(6) in addition to the requirements specified in paragraphs (1) - (5) of this subsection, require the following:

(A) for low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units:

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

(ii) an authorized medical physicist, and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the 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;

(B) for high dose-rate remote afterloader units:

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

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

(C) for gamma stereotactic radiosurgery units and teletherapy units, require that an authorized user and an authorized medical physicist be physically present throughout all patient treatments involving gamma stereotactic radiosurgery units and teletherapy units; and

(D) 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 or dies; and

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

(iii) Dosimetry equipment.

(1) 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:

(A) 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; or

(B) 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 two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic 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.

(2) The licensee shall have available for use a dosimetry system for spot check output measurements, if such measurements are required by this section. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1) of this subsection. 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 requirements of paragraph (1) of this subsection.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison of dosimetry equipment in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's model and serial numbers of the instruments that were calibrated, intercompared, or compared;

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

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

(jjj) Full calibration measurements on teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall performfull calibration measurements on each teletherapy unit as follows:

(A) before the first medical use of the unit; and

(B) before medical use under any of the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than five percent 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

(C) at intervals not to exceed one year.

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

(A) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

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

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

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

(E) "on-off" error; and

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

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals not to exceed one month for cobalt-60, six months for cesium-137, or at intervals consistent with

one percent decay for all other nuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name, model number and serial number of the teletherapy unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations; and

(D) signature of the authorized medical physicist who performed the full calibration.

(kkk) Full calibration measurements on remote afterloader units.

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

(A) before the first medical use of the unit;

(B) before medical use under any of the following conditions:

(i) following replacement of the sealed source;

(ii) following reinstallation of the unit in a new location outside the facility; and

(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;

(C) 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

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

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

(A) the output within plus or minus five percent;

(B) sealed source positioning accuracy to within plus or minus 1 millimeter (mm);

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

(D) length of the sealed source transfer tubes;

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

(F) length of the applicators; and

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

(3) A licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output.

(4) A licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (2) of this subsection, 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.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the sealed source manufacturer that are made in accordance with paragraphs (1) - (5) of this subsection.

(7) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (7) of this subsection shall be performed by an authorized medical physicist.

(9) The licensee shall retain a record of each calibration in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) complete date of the calibration including the month, day, and year;

(B) manufacturer's name, model number and serial number of the remote afterloader unit's sealed source, and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibrations;

(D) signature of the authorized medical physicist of this section; and

(E) results of the autoradiograph required for low dose-rate remote afterloader unit.

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

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

(A) before the first medical use of the unit;

(B) before medical use under the following conditions:

(i) whenever spot check measurements indicate that the output differs by more than five percent 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; and

(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

(C) at intervals not to exceed one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

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

(A) the output within plus or minus three percent;

(B) relative helmet factors;

(C) isocenter coincidence;

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

(E) "on-off" error;

(F) trunnion centricity;

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

(H) helmet microswitches;

(I) emergency timing circuits; and

(J) stereotactic frames and localizing devices (trunnions).

(3) The licensee shall use the dosimetry system described in subsection (iii)(1) of this section to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2)(A) of this subsection

may be made using a dosimetry system that indicates relative dose rates.

(4) The licensee shall make full calibration measurements required by paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) The licensee shall mathematically correct the outputs determined in paragraph (2)(A) of this subsection at intervals not to exceed one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by paragraph (1) of this subsection and physical decay corrections required by paragraph (5) of this subsection shall be performed by an authorized medical physicist.

(7) The licensee shall retain a record of each calibration in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) complete date of the calibration including the month, day and year;

(B) manufacturer's name, model number, and serial number for the unit and the unit's sealed source and the instruments used to calibrate the unit;

(C) results and an assessment of the full calibration; and

(D) signature of the authorized medical physicist who performed the full calibration.

(mmm) Periodic spot checks for teletherapy units.

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

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

(B) "on-off" error;

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

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

(E) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section; and

(F) the difference between the measurement made in subparagraph (E) of this paragraph and the anticipated output, expressed as a percentage of the anticipated output, the value obtained at last full calibration corrected mathematically for physical decay.

(2) The licensee shall perform measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That authorized medical physicist need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (xxx) of this section for inspection by the department.

(3) 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:

(A) electrical interlocks at each teletherapy room entrance;

(B) 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);

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

(D) viewing and intercom systems;

(E) treatment room doors from inside and outside the treatment room; and

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

(4) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(5) If the results of the checks required in paragraph (3) of this subsection 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.

(6) The licensee shall retain a record of each spot check required by paragraphs (1) and (3) of this subsection, in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date of the spot-check;

(B) 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;

(C) assessment of timer linearity and constancy;

(D) calculated "on-off" error;

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

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

(G) the difference between the anticipated output and the measured output;

(H) 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;

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

(J) the signature of the authorized medical physicist who reviewed the record of the spot check.

(nnn) Periodic spot checks for remote afterloader units.

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

(A) before the first use each day of use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit;

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

(C) after each sealed source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (xxx) of this section for inspection by the department.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1) of this subsection, spot checks shall, at a minimum, assure proper operation of the following:

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

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

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

(D) emergency response equipment;

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

(F) timer accuracy;

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

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

(5) If the results of the checks required in paragraph (4) of this subsection 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.

(6) The licensee shall maintain a record, in accordance with subsection (xxx) of this section for inspection by the department, of each check required by paragraph (4) of this subsection. The record shall include the following, as applicable:

(A) date of the spot-check;

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

(C) an assessment of timer accuracy;

(D) 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;

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

(F) the signature of an authorized medical physicist who reviewed the record of the spot-check.

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

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

(A) monthly;

(B) before the first use of the unit on each day of use; and

(C) after each source installation.

(2) The licensee shall perform the measurements required by paragraph (1) of this subsection in accordance with written procedures established by an authorized medical physicist with a specialty in therapeutic radiological physics. That individual need not actually perform the spot check measurements. The licensee shall maintain a copy of the written procedures in accordance with subsection (xxx) of this section for inspection by the department.

(3) The licensee shall have an authorized medical physicist review the results of each spot check and submit a written report to the licensee within 15 days of the spot check.

(4) To satisfy the requirements of paragraph (1)(A) of this subsection, spot checks shall, at a minimum, achieve the following by:

(A) 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

(B) determination of the following:

(i) the output for one typical set of operating conditions measured with the dosimetry system described in subsection (iii)(2) of this section;

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

(iii) sealed source output against computer calculation;

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

(v) "on-off" error; and

(vi) trunnion centricity.

(5) To satisfy the requirements of paragraph (1)(B) and (C) of this subsection, spot checks shall assure proper operation of the following:

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

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

(C) viewing and intercom systems;

(D) timer termination;

(E) radiation monitors used to indicate room exposures; and

(F) emergency "off" buttons.

(6) The licensee shall arrange for prompt repair of any system identified in paragraph (4) of this subsection that is not operating properly.

(7) If the results of the checks required in paragraph (5) of this subsection 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.

(8) The licensee shall retain a record of each check required by paragraphs (4) and (5) of this subsection in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date of the spot check;

(B) 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;

(C) an assessment of timer linearity and accuracy;

(D) the calculated "on-off" error;

(E) a determination of trunnion centricity;

(F) the difference between the anticipated output and the measured output;

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

(H) 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);

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

(J) the signature of an authorized medical physicist who reviewed the record of the spot check.

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

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

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

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

(2) In addition to the periodic spot checks required by subsection (nnn) of this

section, a licensee authorized to use remote afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of the following:

(A) electrical interlocks on treatment area access points;

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

(C) viewing and intercom systems;

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

(E) radiation monitors used to indicate room exposures;

(F) sealed source positioning (accuracy); and

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

(3) In addition to the requirements for checks in paragraph (2) of this subsection, 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.

(4) If the results of the checks required in paragraph (2) of this subsection 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.

(5) The licensee shall maintain a record for inspection by the department, in accordance with subsection (xxx) of this section, of each check required by paragraph (2) of this subsection. The record shall include the following:

(A) date of the check;

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

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

(D) 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

(E) the signature of the individual who performed the check.

(qqq) Radiation surveys.

(1) In addition to the survey requirements of §289.202(p) of this title, a person licensed to use sealed sources in this section shall make surveys to ensure 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 Sealed Source and Device Registry.

(2) The licensee shall make the survey required by paragraph (1) of this subsection 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).

(3) The licensee shall maintain a record for inspection by the department, in accordance with subsection (xxx) of this section, of the radiation surveys required by paragraph (1) of this subsection. The record shall include:

(A) date of the measurements;

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

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

(D) the signature of the individual who performed the test.

(rrr) Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

(1) The licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each sealed source replacement to ensure proper functioning of the sealed source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

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

(3) The licensee shall maintain a record of the inspection and servicing in accordance with subsection (xxx) of this section for inspection by the department. The record shall include the following:

(A) date of inspection;

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

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

(D) the inspector’s radioactive material license number; and

(E) the signature of the inspector.

(sss) Therapy-related computer systems for photon-emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of the following:

(1) the sealed source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

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

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

(ttt) Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in subsection (l) of this section, the licensee shall require an authorized user of a sealed source for a use authorized in subsection (ddd) of this section for:

(1) a physician who is certified by a medical specialty board whose certification process has been recognized by the department, the NRC, or an agreement state and who meets the requirements of paragraph (3) of this subsection. The names of board certifications that have been recognized by the department, the NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification recognized, a specialty board shall require all candidates for certification to:

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

(B) pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) the physician must meet the following requirements:

(A) has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit including the following:

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

(I) radiation physics and instrumentation;

(II) radiation protection;

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

(IV) radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements at a medical facility that is authorized to use radioactive material in subsection (ddd) of this section involving the following:

(I) reviewing full calibration measurements and periodic spot checks;

(II) preparing treatment plans and calculating treatment times;

(III) using administrative controls to prevent a medical event involving the use of radioactive material;

(IV) implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console;

(V) checking and using survey meters; and

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

(iii) completion of three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by clause (ii) of this subparagraph; and

(B) has obtained written attestation that the individual has satisfactorily completed the requirements of paragraphs (2)(A) and (3) of this subsection, and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting

authorized user status. The attestation must be obtained from either:

(i) a preceptor authorized user who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subparagraph (A) of this paragraph; and

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

(uuu) Report and notification of a medical event.

(1) The licensee shall report any event as a medical event, except for an event that results from patient intervention, in which the administration of radioactive material, or radiation from radioactive material, except permanent implant brachytherapy, results in the following:

(A) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem (0.05 Sievert (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

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

(ii) the total dosage delivered differs from the prescribed dosage by 20 percent 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 percent 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 or the wrong radionuclide for a brachytherapy procedure;

(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; or

(C) a dose to the skin or an organ or tissue other than the treatment site that exceeds by

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

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

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

(A) the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(B) the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(C) an administration that includes any of the following:

(i) the wrong radionuclide;

(ii) the wrong individual or human research subject;

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

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

(3) The licensee shall report any event resulting from patient intervention 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.

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

(5) The licensee shall submit a written report to the department within 15 calendar 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) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source and device manufacturer, model number, and serial number, if applicable;

(C) the name of the prescribing physician;

(D) a brief description of the medical event;

(E) why the event occurred;

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

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

(H) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(6) 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 judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee 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.

(7) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individual

affected by the medical event, or to that individual's responsible relatives or guardians.

(8) The licensee shall annotate a copy of the report provided to the department with the following information:

(A) the name of the individual who is the subject of the event; and

(B) an identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

(9) The licensee shall provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 calendar days after the discovery of the event.

(10) The licensee shall retain a copy of the annotated report of the medical event in accordance with subsection (xxx) of this section for inspection by the department.

(vvv) Report and notification of a dose to an embryo/fetus or nursing child.

(1) 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.

(2) 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.

(3) The licensee shall notify the department 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 (1) or (2) of this subsection.

(4) The licensee shall submit a written report to the department no later than 15 calendar days after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with paragraphs (1) or (2) of this subsection. The written report shall include the following, excluding the individual's or child's name or any other information that could lead to identification of the individual or child:

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

(B) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, chemical and physical form, source and/or device manufacturer, model number, and serial number, if applicable;

(C) the name of the prescribing physician;

(D) a brief description of the event;

(E) why the event occurred;

(F) the effect, if any, on the embryo/fetus or the nursing child;

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

(H) certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(5) 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 (1) or (2) 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 judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) The licensee shall annotate a copy of the report provided to the department with the following information:

(A) the name of the individual or the nursing child who is the subject of the event; and

(B) an identification number or if no other identification number is available, the social security number of the individual who is the subject of the event.

(7) The licensee shall provide a copy of the annotated report as described in paragraph (6) of this subsection to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(8) The licensee shall retain a copy of the annotated report as described in paragraph (6) of this subsection of a dose to an embryo/fetus or a nursing child in accordance with subsection (xxx) of this section for inspection by the department.

(www) Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

(1) The licensee shall notify by telephone the department at (512) 458-7460 and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in subsection (ii) of this section at the time of generator elution. The telephone report to the department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(2) The licensee shall submit a written report to the department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (1) of this subsection.

(xxx) Records/documents for department inspection. Each licensee shall maintain copies of the following records/documents at each authorized use site and make them available to the department for inspection, upon reasonable notice.

Figure: 25 TAC §289.256(xxx)

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.201(d)(1)	Records of receipt, transfer, and disposal of radioactive material	Until disposal is authorized by the agency
§289.203(b)(1)(B)	Current applicable sections of this chapter as listed in the radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(B)	Copy of the current radioactive material license	Until termination of the radioactive material license
§289.203(b)(1)(C), §289.256(f)(3)(A)	Current operating, safety, and emergency procedures	Until termination of the radioactive material license
§289.256 (f)(3)(C)(i)	Qualifications of RSO	Duration of employment
§289.256(f)(3)(C)(ii)	Qualifications of authorized users	Duration of employment
§289.256(f)(3)(C)(iii)	Qualifications of authorized medical physicist	Duration of employment
§289.256(f)(3)(C)(iv)	Qualifications of authorized nuclear pharmacist, if applicable	Duration of employment
§289.256(g)(5)	Qualifications and dates of service for temporary RSO	3 years
§289.256(g)(9)(A)	Actions taken by the licensee's management	5 years
§289.256(g)(9)(B)	Authority, duties, and responsibilities of the RSO and the RSO's agreement to implement the radiation safety program.	Until termination of the radioactive material license
§289.256(g)(9)(C)	Document appointing the ARSO	5 years after the ARSO is removed from the license
§289.256(i)(4)	RSC meetings	3 years
§289.256(t)(3)	Written directives	3 years
§289.256(t)(4)(C)	Procedures for administrations requiring a written directive	Until termination of the radioactive material license
§289.256(v)(4)	Calibration of instruments (dose calibrators)	3 years
§289.256(w)(5)	Calibration of survey instruments	3 years
§289.256(x)(6)	Dosage determinations of unsealed radioactive material for medical use	3 years
§289.256(z)(2)	Physical inventory for all sealed source/brachytherapy inventory	3 years
§289.256(bb)(3)	Surveys for ambient radiation exposure rate	3 years
§289.256(cc)(3) §289.256(eee)(2)	Patient release	3 years after date of release

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.256(dd)(3)	Mobile nuclear medicine service client letters	Duration of licensee/client relationship
§289.256(dd)(3)	Mobile nuclear medicine service surveys	3 years
§289.256(ee)(2)	Decay in storage/disposal	3 years
§289.256(ii)(4)	Permissible Molybdenum-99, Strontium-82, and Strontium-85 concentrations	3 years
§289.256(ll)(2)	Safety instructions - unsealed radioactive materials	3 years
§289.256(ss)(3)	Surveys after sealed source implant and removal	3 years
§289.256(tt)(3)	Brachytherapy sealed sources accountability	3 years
§289.256(uu)(2)	Safety instruction to personnel	3 years
§289.256(ww)(4)	Calibration measurements of brachytherapy sealed sources	3 years
§289.256(xx)(3) [§289.256(xx)(2)]	Activity of each Strontium 90 source	Duration of life of source
§289.256(bbb)(2)	Service provider documentation	3 years
§289.256(fff)(4)	Installation, maintenance, adjustment and repair-remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3 years
§289.256(ggg)(6)	Written safety and operating procedures	Until licensee no longer possesses unit
§289.256(ggg)(7)	Instruction/drills for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3 years
§289.256(iii)(3)	Dosimetry equipment calibration, intercomparison and comparison	Until termination of the radioactive material license
§289.256(jjj)(7)	Calibration – teletherapy units	3 years

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§289.256(kkk)(9)	Calibration – remote afterloader units	3 years
§289.256(lll)(7)	Calibration – gamma stereotactic radiosurgery units	3 years
§289.256(mmm)(2)	Written procedures for spot checks- teletherapy units	Until licensee no longer possesses unit
§289.256(mmm)(6)	Spot checks- teletherapy units	Until licensee no longer possesses unit
§289.256(nnn)(2)	Written procedures for spot checks - remote afterloaders	3 years
§289.256(nnn)(6)	Spot checks- remote afterloader	3 years
§289.256(ooo)(2)	Written procedures for spot checks-gamma stereotactic radiosurgery units	3 years
§289.256(ooo)(8)	Spot checks-gamma stereotactic radiosurgery units	3 years
§289.256(ppp)(5)	Technical requirements for mobile remote afterloader units	3 years
§289.256(qqq)(3)	Radiation surveys	Duration of the use of the unit
§289.256(rrr)(3)	Full-inspection servicing records for teletherapy and gamma stereotactic radiosurgery units	Duration of the use of the unit
§289.256(uuu)(9)	Annotated report – medical event	Until termination of the radioactive material license
§289.256(vvv)(8)	Annotated report – dose to embryo/fetus or nursing child	Until termination of the radioactive material license