

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§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 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 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) - (2) (No change.)

(3) An entity that is a "covered entity" as that term is defined in HIPAA (the Health Insurance Portability and Accountability Act of 1996, 45 Code of Federal Regulations, 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.

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

(1) - (19) (No change.)

(20) 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.

(21) [(20)] 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, or a radiation safety officer.

[(21) 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.]

(22) Prescribed dosage--The specified activity or range of activity of unsealed radioactive material [a radiopharmaceutical] 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.

(23) - (36) (No change.)

(d) - (g) (No change.)

(h) Training for radiation safety officer. Except as provided in subsection (l) of this section, the licensee shall require the individual fulfilling the responsibilities of an RSO 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 agency, the NRC, or an agreement state and who meets the requirements in paragraphs (5) and (6) [(4) and (5)] of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation).

(A) (No change.)

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

(i) (No change.)

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

(I) (No change.)

(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) (No change.)

(2) - (6) (No change.)

(i) Radiation safety committee (RSC). Licensees with broad scope authorization 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) - (3) (No change.)

(4) Records documenting the RSC meetings shall be made and maintained for inspection by the agency in accordance with subsection (www) 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 an individual who:

(1) is certified by a specialty board whose certification process has been recognized by the agency, the NRC, an agreement state, or a licensing state and who meets the requirements in paragraphs (3) and (4) of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to meet the following:

(A) (No change.)

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

(i) (No change.)

(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) (No change.)

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

(A) - (B) (No change.)

(C) [(3)] has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (3) of this subsection and paragraphs (1)(A) and (1)(B) or (2)(A) and (2)(B) [and (4)] of this subsection, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation 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) [(4)] has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(k) (No change.)

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

(1) - (2) (No change.)

(3) 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 license for the same uses for which these individuals are authorized.

(m) - (w) (No change.)

(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. [perform the following:]

[(A) record the activity of each dosage; and]

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

(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, agreement state, or licensing state license; **[or]**

(ii) an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration (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) [(2)] For other than unit dosages, this determination shall be made by:

(A) direct measurement of radioactivity; **[or]**

(B) combination of **[direct]** measurement of radioactivity and mathematical calculations; 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, agreement state, or licensing 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) [(3)] Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20%.

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

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

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

(B) - (F) (No change.)

(y) - (dd) (No change.)

(ee) Decay-in-storage.

(1) The licensee may hold radioactive material with a physical half-life of less than or equal to 120 [65] days for decay-in-storage and dispose of it without regard to its radioactivity if the licensee does the following:

(A) - (B) (No change.)

(2) (No change.)

(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 of this title or equivalent NRC, agreement state, or licensing state requirements; or

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

(2) excluding production of PET radionuclides, prepared by [is prepared by one of the following]:

(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)(1)(C)(ii)(VII) of this section[, **or prior to the effective date of this rule, meets the requirements of subsection (l)(2) of this section for imaging and localization studies and unsealed radioactive material requiring a written directive]; or**

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

(3) - (4) (No change.)

(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 agency, the NRC or an agreement state and who meets the requirements in paragraph (3)(C) [(4)] of this subsection. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). 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 that includes the topics listed in paragraph (3)(A) and (B) [(3)] of this subsection; and

(B) (No change.)

(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. The training and experience shall include the following.

(A) (No change.)

(B) 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) - (vi) (No change.)

(C) [(4)] Written [has obtained written] attestation, signed by a preceptor authorized user who meets the requirements of this subsection, subsections (l), (jj), or (nn) of this section, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (1)(A) or (3) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (ff) of this section.

(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 of this title or equivalent NRC, agreement state, or licensing state requirements; or

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

(2) excluding production of PET radionuclides, prepared by [is prepared by one of the following]:

(A) (No change.)

(B) a physician who is an authorized user and who meets the requirements specified in subsections (jj) or (nn) and (jj)(1)(C)(ii)(VII) of this section[, **or prior to the effective date of this rule, meets the requirements of subsection (l)(2) of this section for imaging and localization studies not requiring a written directive**]; or

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

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

(4) [(E)] 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.

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

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

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

(A) more than 0.15 μ Ci of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or [.]

(B) more than 0.02 μ Ci of strontium-82 per mCi of rubidium-82 chloride (0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride) injection; or

(C) more than 0.2 μ Ci of strontium-85 per mCi of rubidium-82 (0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride) injection.

(2) (No change.)

(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) [(3)] If the licensee is required to measure the molybdenum-99 or strontium-82 and strontium-85 concentrations [concentration], the licensee shall retain a record of each measurement in accordance with subsection (www) of this section for inspection by the agency. The record shall include the following [for each measured elution of technetium-99m]:

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

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

(ii) [(B)] time and date of the measurement; and

(iii) [(C)] name of the individual who made the measurement.

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

(i) the ratio of the measures expressed as μ Ci of strontium-82 per mCi of rubidium (kilobecquerel of strontium-82 per megabecquerel of rubidium-82);

(ii) the ratio of the measures expressed as μ Ci of strontium-85 per mCi of rubidium (kilobecquerel of strontium-85 per megabecquerel of rubidium-82);

(iii) time and date of the measurement; and

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

(jj) Training for imaging and localization studies.

(1) 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:

(A) is certified by a medical specialty board whose certification process has been recognized by the agency, the NRC or an agreement state and who meets the requirements of subparagraph (D) of this paragraph. (The names of board certifications that have been recognized by the agency, the NRC, an agreement state, or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation). To have its certification process recognized, a specialty board shall require all candidates for certification to:

(i) - (ii) (No change.)

(B) is an authorized user in accordance with subsection (nn) of this section[;] and meets the requirements of subparagraph (C)(ii)(VII) of this paragraph or equivalent NRC or agreement state requirements; or

(C) has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience shall include the following.

(i) (No change.)

(ii) Work experience under the supervision of an authorized user who meets the requirements in subsection (l) of this section, this subsection, or subclause (VII) of this clause, and subsection (nn) of this section, or equivalent NRC or agreement state requirements involving the following:

(I) - (VII) (No change.)

(iii) **[(D)]** Written [has obtained written] attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or subparagraph (C)(ii)(VII) of this paragraph and subsection (nn) of this section or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of subparagraph (A)(i) or (C)(i) and (ii) [(A)(i) or (C)] of this paragraph and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsections (ff) and (hh) of this section.

(2) (No change.)

(kk) Use of unsealed radioactive material that requires a written directive. A licensee may use any unsealed radioactive material prepared for medical use that requires a written directive **[in accordance with subsection (t) of this section]** that meets the following:

(1) is obtained from:

(A) a manufacturer or preparer licensed in accordance with §289.252 of this title or equivalent NRC, agreement state, or licensing 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 [is prepared by one of the following]:

(A) an authorized nuclear pharmacist; or

(B) (No change.)

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

(3) - (4) (No change.)

(ll) - (mm) (No change.)

(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) (No change.)

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

(A) (No change.)

(B) 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 (for example, in accordance with clause (vi) of this subparagraph) as the individual requesting authorized user status. The work experience shall involve the following:

(i) - (vi) (No change.)

(C) Written [written] attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) and (2)(B)(vi) or (2) of this subsection, and has

achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in paragraph (2) of this subsection shall have experience in administering dosages in the same dosage category or categories (for example, in accordance with paragraph (2)(B)(vi) of this subsection) as the individual requesting authorized user status.

(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) and (B) [paragraphs (3) and (4)] of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements in paragraph (3)(C) of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation); or

(2) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(I) or (II) 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. The training and experience shall include the following.

(A) (No change.)

(B) 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)(B)(vi)(I) or (II) of this section. The work experience shall involve the following:

(i) - (vi) (No change.)

(C) **[(4)]** Written [has obtained written] attestation that the individual has satisfactorily completed the requirements of subparagraphs (A) and (B) of this paragraph [paragraph (3) of this section], and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with

subsection (kk) of this section. The written attestation shall be signed by 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. A preceptor 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)(B)(vi)(I) or (II) of this section.

(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) and (B) [(3)] of this subsection and whose certification has been recognized by the agency, the NRC, an agreement state, or licensing state and who meets the requirements of paragraph (3) [(4)] of this subsection. (The names of board certifications which have been recognized by the agency, the NRC, agreement state or licensing state will be posted on the agency's web page, www.dshs.state.tx.us/radiation);

(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)(B)(vi)(II) 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. The training and experience shall include the following.

(A) (No change.)

(B) 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)(B)(vi)(II) of this section. The work experience shall involve the following:

(i) - (vi) (No change.)

(C) [(4)] Written [has obtained written] attestation that the individual has satisfactorily completed the requirements of subparagraphs (A) and (B) of this paragraph [paragraph (3) of this subsection], and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in accordance with subsection (kk) of this section. The written attestation shall be signed by a preceptor authorized user who meets the requirements in subsection (l) of this section, this subsection or subsection (nn) of this section or equivalent NRC or agreement state requirements. The preceptor

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)(B)(vi)(II) of this section.

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

(1) is an authorized user in accordance with subsection (nn) of this section for uses listed in subsection (nn)(2)(B)(vi)(III) or (IV) of this section or equivalent NRC or agreement state requirements; or

(2) 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 (4) of this subsection; or

(3) (No change.)

(4) has successfully completed training and experience including 80 hours of classroom and laboratory training applicable to parenteral administrations requiring a written directive, of any beta emitting radionuclide or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training and experience shall include the following.

(A) (No change.)

(B) 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, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements of subsection (nn) of this section, shall have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(III) and/or (IV) of this section. The work experience shall involve the following:

(i) - (vi) (No change.)

(C) [(5)] Written [has obtained written] attestation that the individual has satisfactorily completed the requirements of paragraphs (2) or (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive materials requiring a written directive. The written attestation shall be signed by a preceptor 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. A preceptor authorized user, who meets the requirements of

subsection (nn) of this section shall have experience in administering dosages as specified in subsection (nn)(2)(B)(vi)(III) and/or (IV) of this section.

(rr) - (xx) (No change.)

(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) - (4) (No change.)

(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) (No change.)

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

(A) (No change.)

(B) 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 institution, involving the following:

(i) - (vi) (No change.)

(C) Completion of [has completed] 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 (B) of this paragraph; and

(D) Written [has obtained written] attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraph (1)(A) of this subsection or subparagraphs (A) - (C) of this paragraph and has achieved a level of competency sufficient to function independently as an

authorized user of manual brachytherapy for the medical uses authorized in accordance with subsection (rr) of this section.

(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. The training shall include the following.

(A) - (B) (No change.)

(C) Written [has obtained written] attestation, signed by a preceptor authorized user who meets the requirements of subsection (l) of this section, this subsection or subsection (zz) of this section, or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements of paragraphs (1) and (2) of this subsection and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

(bbb) Use of sealed sources for diagnosis.

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

(2) The licensee shall document that the service provider, who is performing installation and source exchange of devices containing sealed source(s) of radioactive material in medical imaging equipment, has a specific license issued by the agency in accordance with §289.252(11) of this title. The documentation shall be maintained for inspection by the agency in accordance with subsection (www) of this section.

(ccc) - (rrr) (No change.)

(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) - (5) (No change.)

(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 to be a physician who:

(1) (No change.)

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

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

(i) - (iii) (No change.)

(iv) radiation biology. **[; and]**

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements of subsection (l) of this section and this subsection or equivalent NRC or agreement state requirements at a medical institution involving the following:

(i) - (vi) (No change.)

(C) Completion of [has completed] 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 subparagraph (B) of this paragraph; and

(D) Written [has obtained written] attestation that the individual has satisfactorily completed the requirements of paragraphs (1)(A) or (2), and (3) of this subsection, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation shall be signed by a preceptor authorized user who meets the requirements in subsection (l) of this section, this subsection, or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) (No change.)

(uuu) - (vvv) (No change.)

(www) Records/documents for agency inspection. Each licensee shall maintain copies of the following records/documents at each authorized use site and make them available to the agency for inspection, upon reasonable notice.

Figure: 25 TAC §289.256(www) [Figure: 25 TAC §289.256(www)]

Figure: 25 TAC §289.256(www)

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
§289.201(g)(7), §289.202(bbb)	Records of leak tests for specific devices and sealed sources	3 years
§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)(1)	Authority of RSO	Duration of employment
§289.256(g)(5)	Qualifications and dates of service for temporary RSO	3 years
§289.256(i)(4)	RSC meetings	3 years
§289.256(t)(3)	Written directives	3 years
§289.256(v)(4)	Calibration of instruments (dose calibrators)	3 years
§289.256(x)(6)	Dosage determinations of unsealed radioactive material for medical use	3 years
§289.256(y)(6)	Physical inventory for all sealed sources received, possessed, and transferred	Until termination of the radioactive material license
§289.256(z)(2)	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
§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)(3)	Molybdenum-99 concentrations	3 years

Figure: 25 TAC §289.256(www)

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Records/Documents
§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 instructions - brachytherapy	3 years
§289.256(ww)(4)	Calibration measurements of brachytherapy sealed sources	3 years
§289.256(xx)(2)	Strontium 90 activity of 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(iii)(3)	Dosimetry equipment calibration, intercomparison and comparison	Until termination of the radioactive material license
§289.256(jjj)(7)	Calibration – teletherapy units	3 years
§289.256(kkk)(9)	Calibration – remote afterleader 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)	Five-year inspection for teletherapy and gamma sterotactic 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

