TITLE 25 HEALTH SERVICES

PART 1 DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 289 RADIATION CONTROL

SUBCHAPTER F LICENSE REGULATIONS

§289.252. Licensing of Radioactive Material.

(a) Purpose. The intent of this section is as follows.

(1) This section provides for the specific licensing of radioactive material.

(2) Unless otherwise exempted, no person shall manufacture, produce, receive, possess, use, transfer, own, or acquire radioactive material except as authorized by the following:

(A) a specific license issued in accordance with this section andany of the following sections:

(i) §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies);

(ii) §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography);

(iii) §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material);

(iv) §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators); or

(v) §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)); or

(B) a general license or general license acknowledgment issued in accordance with §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements).

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

(b) Scope. In addition to the requirements of this section, the following additional requirements are applicable.

(1) All licensees, unless otherwise specified, are subject to the requirements in the following sections:

(A) §289.201 of this title (relating to General Provisions for Radioactive Material);

(B) §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials);

(C) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this title (relating to Hearing and Enforcement Procedures); and

(F) §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(2) Licensees engaged in well logging service operations and tracer studies are subject to the requirements of §289.253 of this title .

(3) Licensees engaged in industrial radiographic operations are subject to the requirements of §289.255 of this title.

(4) Licensees using radioactive material for medical or veterinary use are subject to the requirements of §289.256 of this title.

(5) Licensees using sealed sources in irradiators are subject to the requirements of §289.258 of this title.

(6) Licensees possessing or using naturally occurring radioactive material are subject to the requirements of §289.259 of this title.

(c) Types of licenses. Licenses for radioactive materials are of two types: general and specific.

(1) General licenses provided in §289.251 and §289.259 of this title are effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although the filing of an application for acknowledgement with the department may be required for a particular general license. The general licensee is subject to any other applicable portions of this chapter and any conditions or limitations of the general license.

(2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of this chapter as well as any conditions or limitations specified in the licensing document.

(d) Filing application for specific licenses. The department may, at any time after the filing of the original application, require further statements in order to enable the department to determine whether the application should be denied or the license should be issued.

(1) Applications for specific licenses shall be filed in a manner prescribed by the department.

(2) Each application shall be signed by the chief executive officer or other individual delegated the authority to manage, direct, or administer the licensee's activities.

(3) An application for a license may include a request for a license authorizing one or more activities. The department may require the issuance of separate specific licenses for those activities.

(4) An application for a license may include a request for more than one location of use on the license. The department may require the issuance of a separate license for additional locations that are more than 30 miles from the main site specified on a license.

(5) Each application for a specific license, other than a license exempted from §289.204 of this title, shall be accompanied by the fee prescribed in §289.204 of this title.

(6) Each application shall be accompanied by a completed RC Form 252-1 (Business Information Form).

(7) Each applicant shall demonstrate to the department that the applicant is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the department issues a license. Each licensee shall demonstrate to the department that it remains financially qualified to conduct the licensed activity before a license is renewed. Methods for demonstrating financial qualifications are specified in subsection (jj)(8) of this section. The requirement for demonstration of financial qualification is separate from the requirement specified in subsection (gg) of this section for certain applicants or licensees to provide financial assurance.

(8) If facility drawings submitted in conjunction with the application for a license are prepared by a professional engineer or engineering firm, those drawings shall be final and shall be signed, sealed and dated in accordance with the requirements of the Texas Board of Professional Engineers and Land Surveyors, Title 22, Part 6,Texas Administrative Code (TAC), Chapter 137 .

(9) Applications for licenses shall be processed in accordance with the following time periods.

(A) The first period is the time from receipt of an application by the department to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 60 days.

(B) The second period is the time from receipt of the last item necessary to complete the application to the date of issuance or denial of the license. This time period is 30 days.

(C) These time periods are exclusive of any time period incident to hearings and post-hearing activities required by the Texas Government Code, Chapter 2001.

(10) Except as provided in this paragraph, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall:

(A) identify the source or device by manufacturer and model number as registered in accordance with subsection (v) of this section or with equivalent regulations of the United States Nuclear Regulatory Commission (NRC) or any agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material registered in accordance with subsection (v) of this section; or

(B) contain the information specified in subsection (v)(3) - (4) of this section.

(11) For sources or devices manufactured before October 23, 2012, that are not registered in accordance with subsection (v) of this section or with equivalent regulations of the NRC or any agreement state, and for which the applicant is unable to provide all categories of information specified in subsection (v)(3) - (4) of this section, the application shall include:

(A) all available information identified in subsection (v)(3) - (4) of this section concerning the source, and, if applicable, the device; and

(B) sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include:

(i) a description of the source or device;

(ii) a description of radiation safety features;

(iii) the intended use and associated operating experience; and

(iv) the results of a recent leak test.

(12) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with subsection (v)(8)(A) of this section, the applicant shall supply only the manufacturer, model number, and radionuclide and quantity.

(13) If it is not feasible to identify each sealed source and device individually, the applicant shall propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(14) Notwithstanding the provisions of §289.204(d)(1) of this title, reimbursement of application fees may be granted in the following manner.

(A) In the event the application is not processed in the time periods as stated in paragraph (9) of this subsection, the applicant has the right to request of the director of the Radiation Control Program full reimbursement of all application fees paid in that particular application process. If the director does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(B) Good cause for exceeding the period established is considered to exist if:

(i) the number of applications for licenses to be processed exceeds by 15 percent or more the number processed in the same calendar quarter the preceding year;

(ii) another public or private entity utilized in the application process caused the delay; or

(iii) other conditions existed giving good cause for exceeding the established periods.

(C) If the request for full reimbursement authorized by subparagraph (A) of this paragraph is denied, the applicant may then request a hearing by appeal to the Commissioner of Health for a resolution of the dispute. The appeal will be processed in accordance with Title 1, TAC, Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

(15) Applications for licenses may be denied for the following reasons:

(A) any materially false statement in the application or any statement of fact required under provisions of the Texas Radiation Control Act (Act);

(B) conditions revealed by the application or statement of fact or any report, record, or inspection, or other means that would warrant the department to refuse to grant a license on an application; or

(C) failure to clearly demonstrate how the requirements in this chapter have been addressed.

(16) Action on a specific license application will be considered abandoned if the applicant does not respond within 30 days from the date of a request for any information by the department. Abandonment of such actions does not provide an opportunity for a hearing; however, the applicant retains the right to resubmit the application in accordance with paragraphs (1) - (8) of this subsection.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the department determines that:

(1) the applicant and all personnel who will be handling the radioactive material are qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this chapter in such a manner as to minimize danger to occupational and public health and safety, life, property, and the environment;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to occupational and public health and safety, life, property, and the environment;

(3) the issuance of the license will not be inimical to the health and safety of the public;

(4) the applicant satisfied any applicable special requirement in this section and other sections as specified in subsection (a)(2)(A) of this section;

(5) the radiation safety information submitted for requested sealed source(s) or device(s) containing radioactive material is in accordance with subsection (v) of this section;

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

(7) the applicant submitted adequate operating, safety, and emergency procedures;

(8) the applicant's permanent facility is located in Texas (if the applicant's permanent facility is not located in Texas, reciprocal recognition shall be sought as required by subsection (ee) of this section);

(9) the owner of the property is aware that radioactive material is stored or used on the property, if the proposed facility is not owned by the applicant. The applicant shall provide a written statement from the owner, or from the owner's agent, indicating such. This paragraph does not apply to property owned or held by a government entity or to property on which radioactive material is used under an authorization for temporary job site use;

(10) there is no reason to deny the license as specified in subsections (d)(15) or (x)(9) of this section; and

(11) the applicant shall have a current registration with the Secretary of State to conduct business in the state, unless the applicant is exempt. All applicants using an assumed name in their application shall file an assumed name certificate as required under the Texas Business and Commerce Code, Chapter 71.

(f) RSO.

(1) An RSO shall be designated for every license issued by the department. A single individual may be designated as RSO for more than one license if authorized by the department.

(2) The RSO's documented qualifications shall include as a minimum:

(A) possession of a high school diploma or a certificate of high school equivalency based on the GED test;

(B) completion of the training and testing requirements specified in this chapter for the activities for which the license application is submitted; and

(C) training and experience necessary to supervise the radiation safety aspects of the licensed activity.

(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 specific duties of the RSO which include the following:

(A) to 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) to oversee and approve all phases of the training program for operations and personnel so that appropriate and effective radiation protection practices are taught;

(C) to 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;

(D) to 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;

(E) to 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;

(F) to 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;

(G) to have a thorough knowledge of management policies and administrative procedures of the licensee;

(H) to assume control and have the authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions;

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

(J) to ensure the proper storing, labeling, transport, use and disposal of sources of radiation, storage, and transport containers;

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

(L) to perform a physical inventory of the radioactive sealed sources authorized for use on the license every 6 months and make, maintain, and retain records of the inventory of the radioactive sealed sources authorized for use on the license every six months, to include the following:

(i) isotope(s);

(ii) quantity(ies);

(iii) activity(ies);

(iv) date inventory is performed;

(v) location;

(vi) unique identifying number or serial number; and

(vii) signature of person performing the inventory;

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

(N) to serve as the primary contact with the department; and

(O) to have knowledge of and ensure compliance with federal and state security measures for radioactive material.

(4) The RSO shall ensure that the duties listed in paragraph (3)(A) - (O) 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 a Site RSO designated on the license, 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. A Site RSO shall meet the qualifications in paragraph (2) of this subsection.

(7) Requirements for RSOs for specific licenses for broad scope authorization for research and development. In addition to the requirements in paragraphs (1) and (3) - (6) of this subsection, the RSO's qualifications for specific licenses for broad scope authorization for research and development shall include evidence of the following:

(A) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and 4 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(B) a master's degree in health physics or radiological health and 3 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

(C) 2 years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed and one of the following:

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

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

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

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

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

(D) equivalent qualifications as approved by the department.

(8) The qualifications in paragraph (7)(A) - (D) do not apply to individuals who have been adequately trained and designated as RSOs on licenses issued before October 1, 2000.

(g) Duties and responsibilities of the Radiation Safety Committee (RSC). The duties and responsibilities of the RSC include the following:

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

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

(A) over-exposures;

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

(C) items of non-compliance following an inspection;

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

(4) reviewing the overall compliance status for authorized users;

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

(6) reviewing the audit of the radiation safety program and acting upon the findings;

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

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

(9) evaluating new uses of radioactive material;

(10) reviewing and approving permitted program and procedural changes before implementation; and

(11) having knowledge of and ensuring compliance with federal and state security measures for radioactive material.

(h) Specific licenses of broad scope .

(1) Types of specific licenses of broad scope.

(A) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license. The quantities specified are usually in the multicurie range.

(B) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in subsection (jj)(10) of this section. The possession limit for a Type B specific license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in subsection (jj)(10) of this section. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in subsection (jj)(10) of this section, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(C) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in subsection (jj)(10) of this section. The possession limit for a Type C specific license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in subsection (jj)(10) of this section. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in subsection (jj)(10) of this section, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:

(A) the applicant satisfies the general requirements specified in subsection (e) of this section;

(B) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(C) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, including:

(i) the establishment of a RSC composed of such persons as an RSO, a representative of management, and persons trained and experienced in the safe use of radioactive materials management to fulfill the duties and responsibilities specified in subsection (g) of this section;

(ii) the appointment of a full-time RSO meeting the requirements of subsection (f)(7) or (8) of this section who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) the establishment of appropriate administrative procedures to ensure:

(I) control of procurement and use of radioactive material;

(II) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(III) review, approval, and recording by the RSC of safety evaluations of proposed uses prepared in accordance with subclause (II) of this clause before use of the radioactive material.

(3) An application for a Type B specific license of broad scope will be approved if:

(A) the applicant satisfies the general requirements specified in subsection (e) of this section; and

(B) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) the appointment of an RSO who is qualified by training and experience in radiation protection, and who is available for advice and assistance on safety matters; and

(ii) the establishment of appropriate administrative procedures to ensure:

(I) control of procurement and use of radioactive material;

(II) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(III) review, approval, and recording by the RSO of safety evaluations of proposed uses prepared in accordance with subclause (II) of this clause before use of the radioactive material.

(4) An application for a Type C specific license of broad scope will be approved if:

(A) the applicant satisfies the general requirements specified in subsection (e) of this section;

(B) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(ii) at least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(C) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(5) An application filed pursuant to subsection (e) of this section for a specific license other than one of broad scope will be considered by the department as an application for a specific license of broad scope under this subsection if the applicable requirements of this subsection are satisfied.

(6) The following conditions apply to specific licenses of broad scope.

(A) Unless specifically authorized in accordance with a separate license, persons licensed under this subsection shall not:

(i) conduct tracer studies in the environment involving direct release of radioactive material;

(ii) receive, acquire, own, possess, use, transfer, or import devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(iii) conduct activities for which a specific license issued by the department in accordance with subsections (i) - (u) of this section and §289.255, §289.256, and §289.259 of this title as required;

(iv) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being; or

(v) commercially distribute radioactive materials.

(B) Each Type A specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's RSC.

(C) Each Type B specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's RSO.

(D) Each Type C specific license of broad scope issued under this subsection shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of paragraph (4) of this subsection.

(i) Specific licenses for introduction of radioactive material into products in exempt concentrations. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt in accordance with §289.251 of this title except as specified with a license issued by the NRC.

(j) Specific licenses for commercial distribution of radioactive material in exempt quantities.

(1) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material, byproduct material, or naturally occurring and accelerator-produced radioactive material (NARM) whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission (NRC), Washington, DC 20555 in accordance with Title 10, Code of Federal Regulations (CFR), §32.18.

(2) Licenses issued in accordance with this subsection do not authorize the following:

(A) combining of exempt quantities of radioactive material in a single device;

(B) any program advising persons to combine exempt quantity sources and providing devices for them to do so; and

(C) the possession and use of combined exempt sources, in a single unregistered device, by persons exempt from licensing in accordance with §289.251(e)(2) of this title.

(k) Specific licenses for incorporation of byproduct material or NARM into gas and aerosol detectors. A specific license authorizing the incorporation of byproduct material or NARM into gas and aerosol detectors to be distributed to persons exempt from this chapter shall be issued only by the NRC in accordance with Title 10, CFR, §32.26.

(l) Specific licenses for the manufacture and commercial distribution of devices to persons generally licensed in accordance with §289.251(f)(4)(H) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute devices containing radioactive material to persons generally licensed in accordance with §289.251(f)(4)(H) of this title or equivalent requirements of the NRC or any agreement state will be issued if the department approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) the device can be safely operated by persons not having training in radiological protection;

(ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one year a dose in excess of ten percent of the limits specified in §289.202(f) of this title; and

(iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(I) 15 rems to the whole body; head and trunk; active blood-forming organs; gonads; or lens of eye;

(II) 200 rems to the hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter (cm2); or

(III) 50 rems to other organs;

(B) procedures for disposition of unused or unwanted radioactive material;

(C) each device bears a durable, legible, clearly visible label or labels approved by the department that contain the following in a clearly identified and separate statement:

(i) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(I) For radioactive materials other than NARM, the following statement is appropriate:

Figure: 25 TAC §289.252(l)(1)(C)(iii)(I)

(separate attachment - no change)

(II) For NARM, the following statement is appropriate:

Figure: 25 TAC §289.252(l)(1)(C)(iii)(II)

(separate attachment - no change)

(III) The model and serial number and name of manufacturer or distributor may be omitted from this label provided they are elsewhere stated in labeling affixed to the device.

(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial numbers, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in §289.202(z) of this title, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of §289.251(g)(1) of this title, bears a permanent (for example, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in §289.202(z) of this title.

(F) The device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for radioactive material leakage, the department will consider information that includes the following:

(A) primary containment (sealed source capsule);

(B) protection of primary containment;

(C) method of sealing containment;

(D) containment construction materials;

(E) form of contained radioactive material;

(F) maximum temperature withstood during prototype tests;

(G) maximum pressure withstood during prototype tests;

(H) maximum quantity of contained radioactive material;

(I) radiotoxicity of contained radioactive material; and

(J) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee in accordance with §289.251(f)(4)(H) of this title or in accordance with equivalent regulations of the NRC or any agreement state, be authorized to mount the device, collect the sample to be analyzed by a specific licensee for radioactive material leakage, perform maintenance of the device consisting of replacement of labels, rust and corrosion prevention, and for fixed gauges, repair and maintenance of sealed source holder mounting brackets, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices in accordance with the general license, is unlikely to cause that individual to receive an annual dose in excess of ten percent of the limits specified in §289.202(f) of this title.

(4) Before the device may be transferred, each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall furnish:

(A) a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title;

(B) a copy of the general license in the NRC's or any agreement state's regulation equivalent to §289.251(f)(4)(H) of this title, or alternatively, a copy of the general license in §289.251(f)(4)(H) of this title to each person to whom the licensee directly commercially distributes radioactive material in a device for use in accordance with the general license of the NRC or any agreement state. If certain requirements of the regulations do not apply to the particular device, those requirements may be omitted. If a copy of the general license in §289.251(f)(4)(H) of this title is furnished to such a person, it shall be accompanied by an explanation that the use of the device is regulated by the NRC or any agreement state in accordance with requirements substantially the same as those in §289.251(f)(4)(H) of this title;

(C) a copy of §289.251(g) of this title;

(D) a list of the services that can only be performed by a specific licensee;

(E) information on acceptable disposal options including estimated costs of disposal;

(F) the name or position, address, and phone number of a contact person at the department, the NRC, or any agreement state, from which additional information may be obtained; and

(G) an indication that it is the NRC's policy to issue high civil penalties for improper disposal if the device is commercially distributed to a general licensee of the NRC.

(5) An alternative approach to informing customers may be submitted by the licensee for approval by the department.

(6) In the case of a transfer through an intermediate person, each licensee who commercially distributes radioactive material in a device for use in accordance with the general license in §289.251(f)(4)(H) of this title, shall furnish the information in paragraph (4) of this subsection to the intended user before the initial transfer to the intermediate person.

(7) Each person licensed in accordance with this subsection to commercially distribute devices to generally licensed persons shall:

(A) report to the department all commercial distributions of devices to persons for use in accordance with the general license in §289.251(f)(4)(H) of this title and all receipts of devices from general licensees licensed in accordance with §289.251(f)(4)(H) of this title.

(i) The report shall:

(I) cover each calendar quarter;

(II) be filed within 30 days thereafter;

(III) be submitted on a form prescribed by the department or in a clear and legible report containing all of the data required by the form;

(IV) clearly indicate the period covered by the report;

(V) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(VI) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

(VII) identify an individual by name, title, and phone number who has knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(VIII) identify the type, model and serial number of device, and serial number of sealed source commercially distributed;

(IX) identify the quantity and type of radioactive material contained in the device; and

(X) include the date of transfer.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall also include the information in accordance with paragraph (7)(A)(i) of this subsection for both the intended user and each intermediate person and clearly designate the intermediate person(s).

(iii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the report shall so indicate.

(iv) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(B) report the following to the NRC to include covering each calendar quarter to be filed within 30 days thereafter, clearly indicating the period covered by the report, the identity of the specific licensee submitting the report, and the license number of the specific licensee:

(i) all commercial distributions of such devices to persons for use in accordance with the NRC general license in Title 10, CFR, §31.5 and all receipts of devices from general licensees in areas under NRC jurisdiction including the following:

(I) identity of each general licensee by name and address;

(II) the type, model and serial number of device, and serial number of sealed source commercially distributed;

(III) the quantity and type of radioactive material contained in the device;

(IV) the date of transfer; or

(ii) if the licensee makes changes to a device possessed in accordance with the general license in §289.251(f)(4)(H) of this title, such that the label must be changed to update required information, the report shall identify the licensee, the device, and the changes to information on the device label;

(iii) in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor;

(iv) if no commercial distributions have been made to the NRC licensees during the reporting period; the report shall so indicate;

(C) report to the department or any agreement state all transfers of devices manufactured and commercially distributed in accordance with this subsection for use in accordance with a general license in that state's requirements equivalent to §289.251(f)(4)(H) of this title and all receipts of devices from general licensees.

(i) The report shall:

(I) be submitted within 30 days after the end of each calendar quarter in which such a device is commercially distributed to the generally licensed person;

(II) clearly indicate the period covered by the report;

(III) clearly identify the specific licensee submitting the report and include the license number of the specific licensee;

(IV) identify each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use an alternate address for the licensee shall be submitted along with the information on the actual location of use;

(V) identify an individual by name, position, and phone number who has knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(VI) include the type, model and serial number of the device, and serial number of sealed source commercially distributed;

(VII) include the quantity and type of radioactive material contained in the device; and

(VIII) include the date of receipt.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall also include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) If no commercial distributions have been made to persons in the agreement state during the reporting period, the report shall so indicate.

(iv) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

(D) make, maintain, and retain records required by this paragraph for inspection by the department in accordance with subsection (mm) of this section, including the name, address, and the point of contact for each general licensee to whom the licensee directly or through an intermediate person commercially distributes radioactive material in devices for use in accordance with the general license provided in §289.251(f)(4)(H) of this title, or equivalent requirements of the NRC or any agreement state.

(i) The records shall include the following:

(I) the date of each commercial distribution;

(II) the isotope and the quantity of radioactivity in each device commercially distributed;

(III) the identity of any intermediate person; and

(IV) compliance with the reporting requirements of this subsection.

(ii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(4)(H) of this title during the reporting period, the records shall so indicate.

(8) If a notification of bankruptcy has been made in accordance with subsection (x)(6) of this section or the license is to be terminated, each person licensed in accordance with this subsection shall provide, upon request to the NRC and to any appropriate agreement state, records of final disposition required in accordance with subsection (y)(16)(A) of this section.

(9) Each device that is transferred after February 19, 2002, shall meet the labeling requirements in accordance with paragraph (1)(C) - (E) of this subsection.

(m) Specific licenses for the manufacture, assembly, repair, or initial transfer of luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title. In addition to the requirements in subsection (e) of this section, a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed in accordance with §289.251(f)(4)(B) of this title, will be issued if the department approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.53, 32.54, 32.55, and 32.56, or their equivalent.

(n) Specific licenses for the manufacture or initial transfer of calibration sources containing americium-241 or radium-226 for commercial distribution to persons generally licensed in accordance with §289.251(f)(4)(D) of this title.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture or initially transfer calibration sources containing americium-241, or radium-226 to persons generally licensed in accordance with §289.251(f)(4)(D) of this title will be issued if the department approves the information submitted by the applicant. The information shall satisfy the requirements of Title 10, CFR, §§32.57, 32.58, 32.59, and §70.39 or their equivalent.

(2) Each person licensed in accordance with this subsection shall perform a dry wipe test on each source containing more than 0.1 µCi (3.7 kilobecquerels (kBq)) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with §289.251(f)(4)(D) of this title or equivalent regulations of the NRC or any agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 µCi (0.185 kBq) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.005 µCi (0.185 kBq) of americium-241 or radium-226 by methods described in this paragraph, the source shall be rejected and shall not be transferred to a general licensee in accordance with §289.251(f)(4)(D) of this title or equivalent regulations of the NRC or any agreement state.

(o) Specific licenses for the manufacture and commercial distribution of sealed sources or devices containing radioactive material for medical use. In addition to the requirements in subsection (e) of this section, a specific license to manufacture and commercially distribute sealed sources and devices containing radioactive material to persons licensed in accordance with §289.256 of this title for use as a calibration, transmission, or reference source or for use of sealed sources listed in §289.256(q), (rr), (bbb), and (ddd) of this title will be issued if the department approves the following information submitted by the applicant:

(1) an evaluation of the radiation safety of each type of sealed source or device including the following:

(A) the radioactive material contained, its chemical and physical form, and amount;

(B) details of design and construction of the sealed source or device;

(C) procedures for, and results of, prototype tests to demonstrate that the sealed source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) for devices containing radioactive material, the radiation profile of a prototype device;

(E) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(F) procedures and standards for calibrating sealed sources and devices;

(G) instructions for handling and storing the sealed source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the sealed source or device or attached to a permanent storage container for the sealed source or device, provided that instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label; and

(H) a legend and methods for labeling sources and devices as to their radioactive content;

(2) documentation that the label affixed to the sealed source or device, or to the permanent storage container for the sealed source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of the sealed source or device is licensed by the department for commercial distribution to persons licensed for use of sealed sources in the healing arts or by equivalent licenses of the NRC or any agreement state;

(3) documentation that in the event the applicant desires that the sealed source or device be required to be tested for radioactive material leakage at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the sealed source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the sealed source;

(4) documentation that in determining the acceptable interval for testing radioactive material leakage, information will be considered that includes the following:

(A) primary containment (sealed source capsule);

(B) protection of primary containment;

(C) method of sealing containment;

(D) containment construction materials;

(E) form of contained radioactive material;

(F) maximum temperature withstood during prototype tests;

(G) maximum pressure withstood during prototype tests;

(H) maximum quantity of contained radioactive material;

(I) radiotoxicity of contained radioactive material; and

(J) operating experience with identical sealed sources or devices or similarly designed and constructed sealed sources or devices; and

(5) the source or device has been registered in the Sealed Source and Device Registry.

(p) Specific licenses for the manufacture and commercial distribution of radioactive material for certain *in vitro* clinical or laboratory testing in accordance with the general license. In addition to the requirements in subsection (e) of this section, a specific license to manufacture or commercially distribute radioactive material for use in accordance with the general license in §289.251(f)(4)(G) of this title will be issued if the department approves the following information submitted by the applicant:

(1) documentation that the radioactive material will be prepared for distribution in prepackaged units of:

(A) iodine-125 in units not exceeding 10 µCi (0.37 megabecquerel (MBq)) each;

(B) iodine-131 in units not exceeding 10 µCi (0.37 MBq) each;

(C) carbon-14 in units not exceeding 10 µCi (0.37 MBq) each;

(D) hydrogen-3 (tritium) in units not exceeding 50 µCi (1.85 MBq) each;

(E) iron-59 in units not exceeding 20 µCi (0.74 MBq) each;

(F) cobalt-57 in units not exceeding 10 µCi (0.37 MBq) each;

(G) selenium-75 in units not exceeding 10 µCi (0.37 MBq) each; or

(H) mock iodine-125 in units not exceeding 0.05 µCi (1.85 kBq) of iodine-129 and 0.005 µCi (0.185 kBq) of americium-241 each;

(2) evidence that each prepackaged unit will bear a durable, clearly visible label:

(A) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 µCi (0.37 MBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 µCi (1.85 MBq) of hydrogen-3 (tritium); 20 µCi (0.74 MBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 µCi (1.85 kBq) of iodine-129 and 0.005 µCi (0.185 kBq) of americium-241; and

(B) displaying the radiation caution symbol in accordance with §289.202(z) of this title and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals";

(3) that one of the following statements, as appropriate, or a substantially similar statement appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

(A) option 1:

Figure: 25 TAC §289.252(p)(3)(A)

(separate attachment – no change)

(B) option 2:

Figure: 25 TAC §289.252(p)(3)(B)

(separate attachment - no change)

(4) that the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing the radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements of §289.202(ff) of this title.

(q) Specific licenses for the manufacture and commercial distribution of ice detection devices. In addition to the requirements of subsection (e) of this section, a specific license to manufacture and commercially distribute ice detection devices to persons generally licensed in accordance with §289.251(f)(4)(E) of this title will be issued if the department approves the information submitted by the applicant. This information shall satisfy the requirements of Title 10, CFR, §§32.61 and 32.62.

(r) Specific licenses for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive materials for medical use under §289.256 of this title. (1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture, prepare, or transfer for commercial distribution, radioactive drugs containing radioactive material for use by persons authorized in accordance with §289.256 of this title will be issued if the department approves the following information submitted by the applicant:

(A) evidence that the applicant is at least one of the following:

(i) registered with the United States Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug in accordance with Title 21, CFR, §207.17;

(ii) registered or licensed with a state agency as a drug manufacturer;

(iii) licensed as a pharmacy by the Texas State Board of Pharmacy;

(iv) operating as a nuclear pharmacy within a federal medical institution; or

(v) a positron emission tomography (PET) drug production facility registered with a state agency;

(B) radionuclide data relating to the following:

(i) chemical and physical form;

(ii) maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

(iii) shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees;

(C) labeling requirements including the following:

(i) that each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution shall include the following:

(I) the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;"

(II) the name of the radioactive drug or its abbreviation; and

(III) the quantity of radioactivity at a specified date and time (the time may be omitted for radioactive drugs with a half-life greater than 100 days); and

(ii) that each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution shall include the following:

(I) radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;" and

(II) an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield.

(2) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs and shall have procedures for the use of the instrumentation. The licensee shall measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs before transfer for commercial distribution. In addition, the licensee shall:

(A) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary;

(B) check each instrument for constancy and proper operation at the beginning of each day of use; and

(C) make, maintain, and retain records of the tests and checks required in this paragraph for inspection by the department in accordance with subsection (mm) of this section.

(3) A licensee described in paragraph (1)(A)(iii) or (iv) of this subsection shall prepare radioactive drugs for medical use as defined in §289.256 of this title with the following provisions.

(A) Radioactive drugs shall be prepared by either an authorized nuclear pharmacist, as specified in subparagraphs (B) and (D) of this paragraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(B) A pharmacist shall be allowed to work as an authorized nuclear pharmacist if:

(i) the individual qualifies as an authorized nuclear pharmacist as defined in §289.256 of this title;

(ii) the individual meets the requirements specified in §289.256(k)(2) and (m) of this title, and the licensee has received from the department, an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) the individual is designated as an authorized nuclear pharmacist in accordance with subparagraph (D) of this paragraph.

(C) The actions authorized in subparagraphs (A) and (B) of this paragraph are permitted in spite of more restrictive language in license conditions.

(D) A licensee may designate a pharmacist, as defined in §289.256 of this title, as an authorized nuclear pharmacist if:

(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(ii) the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe or at all other pharmacies before the effective date of this rule as noticed by the NRC or the department.

(E) The licensee shall provide the following to the department:

(i) a copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC, the department, or an agreement state as specified in §289.256(k)(1) of this title ; or

(ii) the department, NRC, or another agreement state license; or

(iii) the permit issued by a broad scope licensee or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(iv) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe or at all other locations of use before the effective date of this rule as noticed by the NRC or the department; and

(v) a copy of the Texas State Board of Pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, in accordance with subparagraph (B)(i) and (iii) of this paragraph, the individual to work as an authorized nuclear pharmacist.

(F) The radiopharmaceuticals for human use shall be processed and prepared 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.

(G) If the authorized nuclear pharmacist elutes generators or processes radioactive material with the reagent kit in a manner that deviates from instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit or in the accompanying leaflet or brochure, a complete description of the deviation shall be made and maintained for inspection by the department in accordance with subsection (mm) of this section.

(4) A licensee shall satisfy the labeling requirements in subsection (r)(1)(C) of this section.

(5) Nothing in this subsection relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.

(s) Specific licenses for the manufacture and commercial distribution of products containing depleted uranium for mass-volume applications.

(1) In addition to the requirements in subsection (e) of this section, a specific license to manufacture products and devices containing depleted uranium for use in accordance with §289.251(f)(3)(D) of this title or equivalent regulations of the NRC or an agreement state, will be issued if the department approves the following information submitted by the applicant:

(A) the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the product or device to provide reasonable assurance that possession, use, or commercial distribution of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one year a radiation dose in excess of ten percent of the limits specified in §289.202(f) of this title; and

(B) reasonable assurance is provided that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of a product or device whose unique benefits are questionable, the department will issue a specific license in accordance with paragraph (1) of this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The department may deny any application for a specific license in accordance with this subsection if the end use(s) of the product or device cannot be reasonably foreseen.

(4) Each person licensed in accordance with paragraph (1) of this subsection shall:

(A) maintain the level of quality control required by the license in the manufacture of the product or device, and in the installation of the depleted uranium into the product or device;

(B) label or mark each unit to:

(i) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(ii) state that the receipt, possession, use, and commercial distribution of the product or device are subject to a general license or the equivalent and the requirements of the NRC or of an agreement state;

(C) assure that before being installed in each product or device, the depleted uranium has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(D) furnish a copy of the following:

(i) the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license in §289.251(f)(3)(D) of this title;

(ii) the NRC's or agreement state's requirements equivalent to the general license in §289.251(f)(3)(D) of this title and a copy of the NRC's or agreement state's certificate; or

(iii) alternately, a copy of the general license in §289.251(f)(3)(D) of this title to each person to whom the licensee commercially distributes depleted uranium in a product or device for use in accordance with the general license of the NRC or an agreement state;

(E) report to the department all commercial distributions of products or devices to persons for use in accordance with the general license in §289.251(f)(3)(D) of this title.

(i) The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is commercially distributed to the generally licensed person and shall include the following:

(I) identity of each general licensee by name and address;

(II) identity of an individual by name and position who may constitute a point of contact between the department and the general licensee;

(III) the type and model number of devices commercially distributed; and

(IV) the quantity of depleted uranium contained in the product or device.

(ii) If no commercial distributions have been made to persons generally licensed in accordance with §289.251(f)(3)(D) of this title during the reporting period, the report shall so indicate;

(F) report to the NRC and each responsible agreement state agency all commercial distributions of industrial products or devices to persons for use in accordance with the general license in the NRC's or agreement state's equivalent requirements to §289.251(f)(3)(D) of this title. The report shall meet the provisions of subparagraph (E)(i) and (ii) of this paragraph; and

(G) make, maintain, and retain records including the name, address, and point of contact for each general licensee to whom the licensee commercially distributes depleted uranium in products or devices for use in accordance with the general license provided in §289.251(f)(3)(D) of this title or equivalent requirements of the NRC or any agreement state. The records shall be maintained for inspection by the department in accordance with subsection (mm) of this section and shall include the date of each commercial distribution, the quantity of depleted uranium in each product or device commercially distributed, and compliance with the report requirements of this section.

(t) Specific licenses for the processing of loose radioactive material for manufacture and commercial distribution. In addition to the requirements in subsection (e) of this section, a license to process loose radioactive material for manufacture and commercial distribution of radioactive material to persons authorized to possess such radioactive material in accordance with this chapter will be issued if the department approves the following information submitted by the applicant:

(1) radionuclides to be used, including the chemical and physical form and the maximum activity of each radionuclide;

(2) intended use of each radionuclide and the sealed sources or other products to be manufactured that includes:

(A) receipt of radioactive material;

(B) chemical or physical preparations;

(C) sealed source construction;

(D) final assembly or processing;

(E) quality assurance testing;

(F) quality control program;

(G) leak testing;

(H) American National Standards Institute (ANSI) testing procedures;

(I) transportation containers;

(J) shipping procedures; and

(K) disposition of unwanted or unused radioactive material;

(3) scaled drawings of the facility to include:

(A) air filtration;

(B) ventilation system;

(C) plumbing; and

(D) radioactive material handling systems and, when applicable, remote handling hot cells;

(4) details of the environmental monitoring program; and

(5) documentation of training as specified in subsection (jj)(1) of this section for all personnel who will be handling radioactive materials.

(u) Specific licenses for other manufacture and commercial distribution of radioactive material. In addition to the requirements in subsection (e) of this section, a license to manufacture and commercially distribute radioactive material to persons authorized to possess such radioactive material in accordance with these requirements will be issued if the department approves the following information submitted by the applicant:

(1) the radionuclides to be used, including the chemical and physical form and the maximum activity of each radionuclide;

(2) the intended use of each radionuclide and the sealed sources or other products to be manufactured that includes:

(A) receipt of radioactive material;

(B) chemical or physical preparations;

(C) sealed source construction;

(D) final assembly or processing;

(E) quality assurance testing;

(F) quality control program;

(G) leak testing;

(H) ANSI testing procedures;

(I) transportation containers;

(J) shipping procedures; and

(K) disposition of unwanted or unused radioactive material;

(3) scaled drawings of radioactive material handling systems; and

(4) documentation of training as specified in subsection (jj)(1) of this section for all personnel who will be handling radioactive material.

(v) Sealed source or device evaluation.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the department for evaluation of radiation safety information about its product and for its registration.

(2) The request for review shall be sent to the department in accordance with §289.201(k) of this title and shall be submitted in duplicate accompanied by the appropriate fee specified in §289.204 of this title.

(3) In order to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property, the request for evaluation of a sealed source or device shall include sufficient information about the:

(A) design;

(B) manufacture;

(C) prototype testing;

(D) quality control program;

(E) labeling;

(F) proposed uses; and

(G) leak testing.

(4) The request for evaluation of a device shall also include sufficient information about:

(A) installation;

(B) service and maintenance;

(C) operating and safety instructions; and

(D) its potential hazards.

(5) The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Section 289.251(e)(1) - (3) of this title includes specific criteria that apply to certain exempt products and §289.251(f) of this title includes specific criteria applicable to certain generally licensed devices. This section includes specific provisions that apply to certain specifically licensed items.

(6) After completion of the evaluation, the department issues a sealed source and device (SS & D) certificate of registration to the person making the request. The SS & D certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of SS & D certificate of registration.

(7) The person submitting the request for evaluation and SS & D certificate of registration of safety information about the product shall manufacture and distribute the product in accordance with:

(A) the statements and representations, including quality control program, contained in the request; and

(B) the provisions of the SS & D certificate of registration.

(8) Authority to manufacture or initially distribute a sealed source or device to specific licensees shall be provided in the license without the issuance of a SS & D certificate of registration in the following cases:

(A) calibration and reference sources shall contain no more than:

(i) 1 mCi (37 MBq) for beta and/or gamma emitting radionuclides; or

(ii) 10 µCi (0.37 MBq) for alpha emitting radionuclides; or

(B) the intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) the intended recipients are licensed in accordance with subsection (h) of this section, §289.256(o) of this title, or equivalent regulations of the NRC or any agreement state; or

(ii) the recipients are authorized for research and development; or

(iii) the sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 20 Ci (740 GBq) of tritium or 200 mCi (7.4 GBq) of any other radionuclide.

(9) After the SS & D certificate of registration is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this section. The department may request such additional information as it considers necessary to conduct its review and the SS & D certificate of registration holder shall provide the information as requested.

(10) Inactivation of SS & D certificate(s) of registration.

(A) An SS & D certificate of registration holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular SS & D certificate of registration issued by the department shall request inactivation of the SS & D certificate of registration. Such a request shall be made to the department by an appropriate method in accordance with §289.201(k) of this title and shall normally be made no later than 2 years after initial distribution of all of the source(s) or device(s) covered by the SS & D certificate of registration has ceased. However, if the SS & D certificate of registration holder determines that an initial transfer was in fact the last initial transfer more than 2 years after that transfer, the SS & D certificate of registration holder shall request inactivation of the SS & D certificate of registration within 90 days of this determination and briefly describe the circumstances of the delay.

(B) If a distribution license is to be terminated in accordance with subsection (y) of this section, the licensee shall request inactivation of its SS & D certificate of registration(s) associated with that distribution license before the department will terminate the license. Such a request for inactivation of the SS & D certificate(s) of registration shall indicate that the license is being terminated and include the associated specific license number.

(C) A specific license to manufacture or initially transfer a source or device covered only by an inactivated SS & D certificate of registration no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices shall be in accordance with any conditions in the SS & D certificate of registration, including in the case of an inactive SS & D certificate of registration.

(w) Issuance of specific licenses.

(1) When the department determines that an application meets the requirements of the Act and the rules of the department, the department will issue a specific license authorizing the proposed activity in such form and containing the conditions and limitations as the department deems appropriate or necessary.

(2) The department may incorporate in any license at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as the department deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety and the environment;

(B) require reports and the keeping of records, and to provide for inspections of activities in accordance with the license as may be appropriate or necessary; and

(C) prevent loss or theft of radioactive material subject to this chapter.

(3) The department may request, and the licensee shall provide, additional information after the license has been issued to enable the department to determine whether the license should be modified in accordance with subsection (dd) of this section.

(x) Specific terms and conditions of licenses.

(1) Each license issued in accordance with this section shall be subject to the applicable provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the department.

(2) No license issued or granted in accordance with this section and no right to possess or utilize radioactive material granted by any license issued in accordance with this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and to applicable rules, now or hereafter in effect, and orders of the department, and shall give its consent in writing.

(3) An application for transfer of license shall include:

(A) the identity, technical and financial qualifications of the proposed transferee; and

(B) financial assurance for decommissioning information required by subsection (gg) of this section.

(4) Each person licensed by the department in accordance with this section shall confine use and possession of the radioactive material licensed to the locations and purposes authorized in the license. Radioactive material shall not be used or stored in residential locations unless specifically authorized by the department.

(5) The licensee shall notify the department, in writing within 15 calendar days, of any of the following changes:

(A) name;

(B) mailing address; or

(C) RSO.

(6) Each licensee shall notify the department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the licensee or its parent company, if the parent company is involved in the bankruptcy.

(7) The notification in paragraph (6) of this subsection shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(8) A copy of the petition for bankruptcy shall be submitted to the department along with the written notification.

(9) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a license, the department may consider the technical competence and compliance history of an applicant or holder of a license. After an opportunity for a hearing, the department may deny an application for a license, an amendment to a license, or renewal of a license if the applicant's compliance history reveals that three or more department actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the license.

(10) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with §289.256 of this title.

(A)The licensee shall make, maintain, and retain a record of the results of each test for inspection by the department in accordance with subsection (mm) of this section.

(B) The licensee shall report the results of any test that exceeds the permissible concentration listed in §289.256(ii) of this title at the time of generator elution, in accordance with §289.256(xxx) of this title.

(11) Licensees shall not hold radioactive waste, sources, or devices not authorized for disposal by decay in storage, and that are not in use for longer than 24 months following the last principal activity use. Sources and devices kept in standby for future use may be excluded from the 24-month time limit if the department approves a plan for future use. A plan for an alternative disposal timeframe may be submitted by the licensee if the 24-month time limit cannot be met. Licensees shall submit plans to the department at least 30 days before the end of the 24 months of nonuse.

(y) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(1) Except as provided in paragraph (2) of this subsection and subsection (z)(2) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(2) Expiration of the specific license does not relieve the licensee of the requirements of this chapter.

(3) All license provisions continue in effect beyond the expiration date, with respect to possession of radioactive material until the department notifies the former licensee in writing that the provisions of the license are no longer binding. During this time, the former licensee shall:

(A) be limited to actions involving radioactive material that are related to decommissioning; and

(B) continue to control entry to restricted areas until the location(s) is suitable for release for unrestricted use in accordance with the requirements in §289.202(ddd) of this title.

(4) Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the department in writing and either begin decommissioning a site, or any separate building or outdoor area that contains residual radioactivity, so that the building and outdoor area is suitable for release in accordance with §289.202(eee) of this title, or submit within 12 months of notification a decommissioning plan, if required by paragraph (7) of this subsection, and begin decommissioning upon approval of that plan if:

(A) the license has expired or has been revoked in accordance with this subsection or subsection (dd) of this section;

(B) the licensee has decided to permanently cease principal activities, as defined in §289.201(b) of this title, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with department requirements;

(C) no principal activities at an entire site as specified in the license have been conducted for a period of 24 months; or

(D) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with §289.202(eee) of this title.

(5) Coincident with the notification required by paragraph (4) of this subsection, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in accordance with subsection (gg) of this section in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance shall be increased, or may be decreased, as appropriate, with department approval, to cover the detailed cost estimate for decommissioning established in accordance with paragraph (10)(E) of this subsection.

(A) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so in accordance with subsection (gg) of this section.

(B) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site, with the approval of the department.

(6) The department may grant a request to delay or postpone initiation of the decommissioning process if the department determines that such relief is not detrimental to the occupational and public health and safety and is otherwise in the public interest. The request shall be submitted no later than 30 days before notification in accordance with paragraph (4) of this subsection. The schedule for decommissioning set forth in paragraph (4) of this subsection may not commence until the department has made a determination on the request.

(7) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(A) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(B) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(C) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(D) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(8) The department may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph (4) of this subsection if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the occupational and public health and safety and is otherwise in the public interest.

(9) The procedures listed in paragraph (7) of this subsection may not be carried out before approval of the decommissioning plan.

(10) The proposed decommissioning plan for the site or separate building or outdoor area shall include the following:

(A) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(B) a description of planned decommissioning activities;

(C) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(D) a description of the planned final radiation survey;

(E) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(F) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in paragraph (15) of this subsection.

(11) The proposed decommissioning plan will be approved by the department if the information in the plan demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(12) Except as provided in paragraph (14) of this subsection, licensees shall complete decommissioning of the site or separate building or outdoor areas as soon as practicable but no later than 24 months following the initiation of decommissioning.

(13) Except as provided in paragraph (14) of this subsection, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(14) The department may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted by consideration of the following:

(A) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(B) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(C) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(D) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(E) other site-specific factors that the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(15) As the final step in decommissioning, the licensee shall do the following:

(A) certify the disposition of all licensed material, including accumulated wastes; and

(B) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title. The licensee shall do the following, as appropriate:

(i) report the following levels:

(I) gamma radiation in units of microroentgen per hour (µR/hr) (millisieverts per hour (mSv/hr)) at 1 meter (m) from surfaces;

(II) radioactivity, including alpha and beta, in units of disintegrations per minute (dpm) or microcuries (µCi) (megabecquerels (MBq)) per 100 square centimeters (cm2) for surfaces;

(III) µCi (MBq) per milliliter for water; and

(IV) picocuries (pCi) (becquerels (Bq)) per gram (g) for solids such as soils or concrete; and

(ii) specify the manufacturer's name and model and serial number of survey instrument(s) used and certify that each instrument is properly calibrated in accordance with §289.202(p) of this title and tested.

(16) The department will provide written notification to specific licensees, including former licensees with provisions continued in effect beyond the expiration date in accordance with paragraph (3) of this subsection, that the provisions of the license are no longer binding. The department will provide such notification when the department determines that:

(A) radioactive material has been properly disposed;

(B) reasonable effort has been made to eliminate residual radioactive contamination, if present;

(C) a radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title, or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the radiological requirements for license termination specified in §289.202(ddd) of this title; and

(D) any outstanding fees in accordance with §289.204 of this title are paid and any outstanding notices of violations of this chapter or of license conditions are resolved.

(17) Each licensee shall submit to the department all records required by §289.202(nn)(3) of this title before the license is terminated.

(z) Renewal of licenses.

(1) Requests for renewal of specific licenses shall be filed in accordance with subsection (d)(1) - (4) and (6) - (8) of this section. In any application for renewal, the applicant may incorporate drawings by clear and specific reference (for example, title, date and unique number of drawing), if no modifications have been made since previously submitted.

(2) In any case in which a licensee, not less than 30 days before expiration of an existing license, has filed a request in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the request has been finally determined by the department. In any case in which a licensee, not more than 90 days after the expiration of an existing license, has filed a request in proper form for renewal or for a new license authorizing the same activities, the department may reinstate the license and extend the expiration until the request has been finally determined by the department. The requirements in this subsection are subject to the provisions of Texas Government Code, §2001.054.

(3) An application for technical renewal of a license will be approved if the department determines that the requirements of subsection (e) of this section have been satisfied.

(aa) Amendment of licenses at request of licensee.

(1) Requests for amendment of a license shall be filed in accordance with subsection (d)(1) - (4) of this section shall be signed by management or the RSO, and shall specify the respects in which the licensee desires a license to be amended and the grounds for the amendment.

(2) Requests for amendments to delete a subsite from a license shall be filed in accordance with subsections (d)(1) and (2) and (y)(13) and (15) of this section.

(bb) Department action on requests to renew or amend. In considering a request by a licensee to renew or amend a license, the department will apply the criteria in subsection (e) of this section as applicable.

(cc) Transfer of material.

(1) No licensee shall transfer radioactive material except as authorized in accordance with this chapter. This subsection does not include transfer for commercial distribution.

(2) Except as otherwise provided in a license and subject to the provisions of paragraphs (3) and (4) of this subsection, any licensee may transfer radioactive material:

(A) to the department (A licensee may transfer material to the department only after receiving prior approval from the department);

(B) to the United States Department of Energy (DOE);

(C) to any person exempt from this section to the extent permitted in accordance with such exemption;

(D) to any person authorized to receive such material in accordance with the terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the NRC, or any agreement state, or to any person otherwise authorized to receive such material by the federal government or any agency of the federal government, the department, or any agreement state; or

(E) as otherwise authorized by the department in writing.

(3) Before transferring radioactive material to a specific licensee of the department, the NRC, or any agreement state, or to a general licensee who is required to register with the department, the NRC, or any agreement state before receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by paragraph (3) of this subsection are acceptable.

(A) The transferor may possess and have read a current copy of the transferee's specific license.

(B) When a current copy of the transferee's specific license described in subparagraph (A) of this paragraph is not readily available or when a transferor desires to verify that information received is correct or up-to-date, the transferor may obtain and record confirmation from the department, the NRC, or any agreement state that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of subsection (ff) of this section.

(6) Requirements for transfer of small quantities of source material.

(A) An application for a specific license to initially transfer source material for use in accordance with §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state, will be approved if:

(i) the applicant satisfies the general requirements specified in subsection (e) of this section; and

(ii) the applicant submits adequate information on, and the department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(B) Quality control, labeling, safety instructions, and records and reports. Each person licensed under subparagraph (A) of this paragraph shall:

(i) label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(ii) ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(iii) provide the information specified in this clause to each person to whom source material is transferred for use under §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(I) a copy, as applicable, of §289.251(f)(3) of this title; Title 10, CFR, §40.22; or the equivalent agreement state regulation that applies; and of this subsection; Title 10, CFR, §40.51; or the equivalent agreement state regulations that apply; and

(II) appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(iv) report transfers as follows:

(I) File a report with the department and the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

(-a-) the name, address, and license number of the person who transferred the source material;

(-b-) for each general licensee under §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(-c-) the total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(II) File a report with each responsible agreement state agency that identifies all persons, operating under §289.251(f)(3) of this title; Title 10, CFR, §40.22, or equivalent regulations of any agreement state to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state being reported to:

(-a-) the name, address, and license number of the person who transferred the source material; and

(-b-) the name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(-c-) the total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state.

(III) The following are to be submitted to the department by January 31 of each year:

(-a-) each report required by subclauses (I) and (II) of this clause covering all transfers for the previous calendar year;

(-b-) if no transfers were made during the current period to persons generally licensed in accordance with §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state, a report to the department indicating so; and

(-c-) if no transfers have been made to general licensees in a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state upon request of that agency.

(C) Records.

(i) The licensee shall maintain all information that supports the reports required by this paragraph concerning each transfer to a general licensee for inspection by the department in accordance with subsection (mm) of this section.

(ii) The licensee who transferred the material shall retain each record of transfer of radioactive material until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(dd) Modification, suspension, and revocation of licenses.

(1) The terms and conditions of all licenses shall be subject to revision or modification. A license may be modified, suspended or revoked by reason of amendments to the Act, by reason of rules in this chapter, or orders issued by the department.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any of the following:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the department to refuse to grant a license on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the license, or order of the department; or

(D) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(3) Each specific license revoked by the department ends at the end of the day on the date of the department’s final determination to revoke the license, or on the revocation date stated in the determination, or as otherwise provided by the department order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no license shall be suspended or revoked unless, before the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(ee) Reciprocal recognition of licenses.

(1) Subject to this section, any person who holds a specific license from the NRC or any agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is granted a general license to conduct the activities authorized in such licensing document within the State of Texas provided that:

(A) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(B) the out-of-state licensee notifies the department in writing at least three working days before engaging in such activity. If, for a specific case, the three-working-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the department, obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities in accordance with the general license provided in this subsection. Such notification shall include:

(i) the exact location, start date, duration, and type of activity to be conducted;

(ii) the identification of the radioactive material to be used;

(iii) the name(s) and in-state address(es) of the individual(s) performing the activity;

(iv) a copy of the applicant's pertinent license;

(v) a copy of the licensee's operating, safety, and emergency procedures;

(vi) a fee as specified in §289.204 of this title; and

(vii) a copy of the completed RC Form 252-1 (Business Information Form);

(C) the out-of-state licensee complies with all applicable rules of the department and with all the terms and conditions of the licensee's licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the department;

(D) the out-of-state licensee supplies such other information as the department may request;

(E) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used in accordance with the general license provided in this subsection except by transfer to a person:

(i) specifically licensed by the department, the NRC, or any agreement state to receive such material, or

(ii) exempt from the requirements for a license for such material in accordance with §289.251(e)(1) of this title; and

(F) the out-of-state licensee shall have the following documents in their possession at all times when conducting work in Texas, and make them available for department review upon request:

(i) a copy of the department letter granting the licensee reciprocal recognition of their out-of-state license;

(ii) a copy of the licensee's operating and emergency procedures;

(iii) a copy of the licensee's radioactive material license;

(iv) a copy of all applicable sections of 25 TAC, Chapter 289; and

(v) a copy of the completed RC Form 252-3 notifying the department of the licensee's intent to work in Texas.

(2) In addition to the provisions of paragraph (1) of this subsection, any person who holds a specific license issued by the NRC or any agreement state authorizing the holder to manufacture, transfer, install, or service the device described in §289.251(f)(4)(H) of this title or in Title 10, CFR, §150.20, within areas subject to the jurisdiction of the licensing body, is granted a general license to install, transfer, demonstrate, or service the device in the State of Texas provided that:

(A) the person files a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in the State of Texas. Each report shall identify by name and address, each general licensee to whom the device is transferred, the type of device transferred by manufacturer's name, model and serial number of the device, and serial number of the sealed source, and the quantity and type of radioactive material contained in the device;

(B) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the NRC or any agreement state;

(C) the person assures that any labels required to be affixed to the device in accordance with requirements of the authority that licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(D) the holder of the specific license furnishes to each general licensee to whom the holder of the specific license transfers the device, or on whose premises the holder of the specific license installs the device, a copy of the general license contained in §289.251(f)(4)(H) of this title.

(3) The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed in accordance with the licensing document, upon determining that the action is necessary in order to prevent undue hazard to occupational and public health and safety and the environment.

(ff) Preparation of radioactive material for transport. Requirements for the preparation of radioactive material for transport are specified in §289.257 of this title.

(gg) Financial assurance and record keeping for decommissioning.

(1) The applicant for a specific license or renewal of a specific license, or holder of a specific license, authorizing the possession and use of radioactive material shall submit and receive written authorization for a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the department to engage a third party to decommission the site(s) specified on the license for the following situations:

(A) when unsealed radioactive material requested or authorized on the license, with a half-life greater than 120 days, is in quantities exceeding 105 times the applicable quantities set forth in subsection (jj)(2) of this section;

(B) when a combination of the unsealed radionuclides requested or authorized on the license, with a half-life greater than 120 days, results in the R of the radionuclides divided by 105 being greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each radionuclide to the applicable value in subsection (jj)(2) of this section;

(C) when sealed sources or plated foils requested or authorized on the license, with a half-life greater than 120 days and in quantities exceeding 1012 times the applicable quantities set forth in subsection (jj)(2) of this section (or when a combination of isotopes is involved if R, as defined in this subsection, divided by 1012 is greater than 1), shall submit a decommissioning funding plan as described in paragraph (4) of this subsection; or

(D) when radioactive material requested or authorized on the license is in quantities more than 100 mCi (3.7 gigabecquerels (GBq)) of source material in a readily dispersible form.

(2) The applicant for a specific license or renewal of a specific license or the holder of a specific license authorizing possession and use of radioactive material as specified in paragraph (3) of this subsection shall either:

(A) submit a decommissioning funding plan as described in paragraph (4) of this subsection in an amount sufficient to allow the department to engage a third party to decommission the site(s) specified on the license; or

(B) submit financial assurance for decommissioning in the amount in accordance with paragraph (3) of this subsection using one of the methods described in paragraph (6) of this subsection in an amount sufficient to allow the department to engage a third party to decommission the site(s) specified on the license.

(3) The required amount of financial assurance for decommissioning is determined by the quantity of material authorized by the license and is determined as follows:

(A) $1,125,000 for quantities of material greater than 104 but less than or equal to 105 times the applicable quantities in subsection (jj)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 104 is greater than 1 but R divided by 105 is less than or equal to 1);

(B) $225,000 for quantities of material greater than 103 but less than or equal to 104 times the applicable quantities in subsection (jj)(2) of this section in unsealed form. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 103 is greater than 1 but R divided by 104 if less than or equal to 1);

(C) $113,000 for quantities of material greater than 1010 but less than or equal to 1012 times the applicable quantities in subsection (jj)(2) of this section in sealed sources or plated foils. (For a combination of radionuclides, if R, as defined in paragraph (1) of this subsection, divided by 1010 is greater than 1, but R divided by 1012 is less than or equal to 1); or

(D) $225,000 for quantities of source material greater than 10 mCi (0.37 GBq) but less than or equal to 100 mCi (3.7 GBq) in a readily dispersible form.

(4) Each decommissioning funding plan shall:

(A) be submitted for review and approval and shall contain the following:

(i) a detailed cost estimate for decommissioning in an amount reflecting:

(I) the cost of an independent contractor to perform all decommissioning activities;

(II) the cost of meeting the criteria of §289.202(ddd)(2) of this title for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of §289.202(ddd)(3) of this title, the cost estimate may be based on meeting the criteria of §289.202(ddd)(3) of this title;

(III) the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(IV) an adequate contingency factor.

(ii) identification of and justification for using the key assumptions contained in the detailed cost estimate;

(iii) a description of the method of assuring funds for decommissioning from paragraph (6) of this subsection, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) a signed original of the financial instrument obtained to satisfy the requirements of paragraph (6) of this subsection (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning); and

(B) at the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan, be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan shall update the information submitted with the original or prior approved plan, and shall specifically consider the effect of the following events on decommissioning costs:

(i) spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) waste inventory increasing above the amount previously estimated;

(iii) waste disposal costs increasing above the amount previously estimated;

(iv) facility modifications;

(v) changes in authorized possession limits;

(vi) actual remediation costs that exceed the previous cost estimate;

(vii) onsite disposal; and

(viii) use of a settling pond.

(5) Financial assurance in conjunction with a decommissioning funding plan shall be submitted as follows:

(A) for an applicant for a specific license, financial assurance as described in paragraph (6) of this subsection, may be obtained after the application has been approved and the license issued by the department, but shall be submitted to the department before receipt of licensed material; or

(B) for an applicant for renewal of a specific license, or a holder of a specific license, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (6) of this subsection shall be submitted with the decommissioning funding plan.

(6) Financial assurance for decommissioning shall be provided by one or more of the following methods. The financial instrument obtained shall be continuous for the term of the license in a form prescribed by the department . The applicant or licensee shall obtain written approval of the financial instrument or any amendment to it from the department.

(A) Prepayment. Prepayment is the deposit into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(B) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (jj)(3) of this section. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in subsection (jj)(4) of this section. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in subsection (jj)(5) of this section. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in subsection (jj)(6) of this section. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions.

(i) The surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more before the renewal date, the issuer notifies the department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be paid to the beneficiary automatically before the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance shall be payable in the State of Texas to the Radiation and Perpetual Care Account.

(iii) The surety method or insurance shall remain in effect until the department has terminated the license.

(C) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions shall be in accordance with subparagraph (B) of this paragraph.

(D) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount in accordance with paragraph (3) of this subsection, and indicating that funds for decommissioning will be obtained when necessary.

(E) When a governmental entity is assuming custody and ownership of a site, there shall be an arrangement that is deemed acceptable by such governmental entity.

(7) Each person licensed in accordance with this section shall make, maintain, and retain records of information important to the safe and effective decommissioning of the facility in an identified location for inspection by the department in accordance with §289.252(mm) of this section. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the department considers important to decommissioning consists of the following:

(A) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations;

(B) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations;

(C) except for areas containing only sealed sources (provided the sealed sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

(i) all areas designated and formerly designated as restricted areas as defined in §289.201(b) of this title;

(ii) all areas outside of restricted areas that require documentation under subparagraph (A) of this paragraph;

(iii) all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in §289.202(ddd) of this title, or meet the requirements for approval of disposal under §289.202(ff) - (kk) of this title; and

(D) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds.

(8) Any licensee who has submitted an application before January 1, 1995, for renewal of license in accordance with this section shall provide financial assurance for decommissioning in accordance with paragraphs (1) and (2) of this subsection.

(hh) Emergency plan for responding to a release.

(1) A new or renewal application for each specific license to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in subsection (jj)(7) of this section shall contain either:

(A) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive material would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(B) an emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted in accordance with paragraph (1)(A) of this subsection:

(A) the radioactive material is physically separated so that only a portion could be involved in an accident;

(B) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) the release fraction in the respirable size range would be lower than the release fraction in subsection (jj)(7) of this section due to the chemical or physical form of the material;

(D) the solubility of the radioactive material would reduce the dose received;

(E) facility design or engineered safety features in the facility would cause the release fraction to be lower than that in subsection (jj)(7) of this section;

(F) operating restrictions or procedures would prevent a release fraction as large as that in subsection (jj)(7) of this section; or

(G) other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted in accordance with paragraph (1)(B) of this subsection shall include the following information.

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department; also, responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements in accordance with the Emergency Planning and Community Right-to-Know-Act of 1986, Title III, Publication L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the department.

(J) Training. A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations at intervals not to exceed three months and biennial onsite exercises to test response to simulated emergencies. Communications checks with offsite response organizations shall include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities in accordance with the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Publication L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the 60 days to the department with the emergency plan.

(ii) Physical protection of category 1 and category 2 quantities of radioactive material.

(1) Specific exemptions. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of paragraphs (2) - (23) of this subsection, except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kilograms (4,409 pounds) is not exempt from the requirements of this subsection. The licensee shall implement the following requirements to secure the radioactive waste:

(A) use continuous physical barriers that allow access to the radioactive waste only through established access control points;

(B) use a locked door or gate with monitored alarm at the access control point;

(C) assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

(D) immediately notify the local law enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

(2) Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.

(A) General.

(i) Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this paragraph and paragraphs (3) - (8) of this subsection.

(ii) An applicant for a new license and each licensee that would become subject to the requirements of this paragraph and paragraphs (3) - (8) of this subsection upon application for modification of its license shall implement the requirements of this paragraph and paragraphs (3) - (8) of this subsection, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(iii) Any licensee that has not previously implemented the security orders or been subject to this paragraph and paragraphs (3) - (8) of this subsection shall implement the provisions of these paragraphs before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General performance objective. The licensee's access authorization program must ensure that the individuals specified in subparagraph (C)(i) of this paragraph are trustworthy and reliable.

(C) Applicability.

(i) Licensees shall subject the following individuals to an access authorization program:

(I) any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(II) reviewing officials.

(ii) Licensees need not subject the categories of individuals listed in paragraph (6)(A)(i) - (xiii) of this subsection to the investigation elements of the access authorization program.

(iii) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

(iv) Licensees may include individuals needing access to safeguards information-modified handling in accordance with Title 10, CFR, Part 73, in the access authorization program under this paragraph and paragraphs (3) - (8) of this subsection.

(3) Access authorization program requirements.

(A) Granting unescorted access authorization.

(i) Licensees shall implement the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection for granting initial or reinstated unescorted access authorization.

(ii) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by paragraph (10)(C) of this subsection before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.)

(B) Reviewing officials.

(i) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

(ii) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide to the department under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with paragraph (4)(C) of this subsection.

(iii) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

(iv) Reviewing officials cannot approve other individuals to act as reviewing officials.

(v) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(I) the individual has undergone a background investigation that included fingerprinting and a Federal Bureau of Investigation (FBI) criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(II) the individual is subject to a category listed in paragraph (6)(A) of this subsection.

(C) Informed consent.

(i) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of paragraph (4)(B) of this subsection. A signed consent must be obtained before any reinvestigation.

(ii) The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(I) if an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(II) the withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(D) Personal history disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection is sufficient cause for denial or termination of unescorted access.

(E) Determination basis.

(i) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection.

(ii) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(iii) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(iv) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

(v) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall:

(I) remove the person from the approved list as soon as possible, but no later than 7 working days; and

(II) take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(F) Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must:

(i) include provisions for the notification of individuals who are denied unescorted access;

(ii) include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization; and

(iii) contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(G) Right to correct and complete information.

(i) Before any final adverse determination, licensees shall provide each individual subject to paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for inspection by the department in accordance with subsection (mm) of this section.

(ii) If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in Title 28, CFR, §§16.30 - 16.34. In the latter case, the FBI will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(H) Records. The licensee shall make, maintain, and retain the following records/documents for inspection by the department in accordance with subsection (mm) of this section. The licensee shall maintain superseded versions or portions of the following records/documents for inspection by the department in accordance with subsection (mm) of this section:

(i) documentation regarding the trustworthiness and reliability of individual employees;

(ii) a copy of the current access authorization program procedures; and

(iii) the current list of persons approved for unescorted access authorization.

(4) Background investigations.

(A) Initial investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

(i) fingerprinting and an FBI identification and criminal history records check in accordance with paragraph (5) of this subsection;

(ii) verification of true identity. Licensees shall:

(I) verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be;

(II) review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information;

(III) document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with paragraph (7) of this subsection;

(IV) certify in writing that the identification was properly reviewed; and

(V) maintain the certification and all related documents for inspection by the department in accordance with subsection (mm) of this section;

(iii) employment history verification. Licensees shall:

(I) complete an employment history verification, including military history; and

(II) verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

(iv) verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

(v) character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks as specified in paragraphs (2) and (3), this paragraph, and paragraphs (5) - (8) of this subsection must be limited to whether the individual has been and continues to be trustworthy and reliable;

(vi) the licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

(vii) if a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

(B) Grandfathering.

(i) Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material as specified in the fingerprint orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

(ii) Individuals who have been determined to be trustworthy and reliable in accordance with Title 10, CFR, Part 73, or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under Title 10, CFR, Part 73, or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(C) Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with paragraph (5) of this subsection. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

(5) Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.

(A) General performance objective and requirements.

(i) Except for those individuals listed in paragraph (6) of this subsection and those individuals grandfathered under paragraph (4)(B) of this subsection, each licensee subject to the requirements of paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection shall:

(I) fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material;

(II) transmit all collected fingerprints to the NRC for transmission to the FBI; and

(III) use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

(ii) The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

(iii) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

(I) the individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(II) the previous access was terminated under favorable conditions.

(iv) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted in accordance with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, the fingerprint orders, or Title 10, CFR, Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the requirements of paragraph (7)(C) of this subsection.

(v) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(B) Prohibitions.

(i) Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(I) an arrest more than one year old for which there is no information of the disposition of the case; or

(II) an arrest that resulted in dismissal of the charge or an acquittal.

(ii) Licensees may not use information received from a criminal history records check obtained under paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(C) Procedures for processing of fingerprint checks.

(i) For the purpose of complying with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, licensees shall use an appropriate method listed in Title 10, CFR, §37.7, to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, 11545 Rockville Pike,Rockville, Maryland 20852 , one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov*.* Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html*.*

(ii) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier’s check, money order, or electronic payment, made payable to “U.S. NRC.” (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC’s public website. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.htmland see the link for How do I determine how much to pay for the request?).

(iii) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

(6) Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(A) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals before granting unescorted access to category 1 or category 2 quantities of radioactive materials:

(i) an employee of the NRC or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(ii) a member of Congress;

(iii) an employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

(iv) the governor of a state or his or her designated state employee representative;

(v) federal, state, or local law enforcement personnel;

(vi) state radiation control program directors and state homeland security advisors or their designated state employee representatives;

(vii) agreement state employees conducting security inspections on behalf of the NRC under an agreement executed as specified in §274.1 of the Atomic Energy Act;

(viii) representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(ix) emergency response personnel who are responding to an emergency;

(x) commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

(xi) package handlers at transportation facilities such as freight terminals and railroad yards;

(xii) any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall maintain this documentation for inspection by the department in accordance with subsection (mm) of this section; and

(xiii) any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall maintain and retain the documentation for inspection by the department in accordance with subsection (mm) of this section.

(B) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall maintain this documentation for inspection by the department in accordance with subsection (mm) of this section. These programs include:

(i) National Agency Check;

(ii) Transportation Worker Identification Credentials (TWIC) under Title 49, CFR, Part 1572;

(iii) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under Title 27, CFR, Part 555;

(iv) Health and Human Services security risk assessments for possession and use of select agents and toxins under Title 42, CFR, Part 73;

(v) Hazardous Material security threat assessment for hazardous material endorsement to commercial driver’s license under Title 49, CFR, Part 1572; and

(vi) Customs and Border Protection's Free and Secure Trade (FAST) Program.

(7) Protection of information.

(A) Each licensee who obtains background information on an individual under paragraphs (2) - (6), this paragraph, or paragraph (8) of this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(B) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(C) The personal information obtained on an individual from a background investigation may be provided to another licensee:

(i) upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

(ii) the recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(D) The licensee shall make background investigation records obtained under paragraphs (2) - (6), this paragraph, and paragraph (8) of this subsection available for examination by an authorized representative of the department to determine compliance with the regulations and laws.

(E) The licensee shall maintain all fingerprint and criminal history records on an individual (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, for inspection by the department in accordance with subsection (mm) of this section.

(8) Access authorization program review.

(A) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of paragraphs (2) - (7) and this paragraph of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall review the access program content and implementation at least every 12 months.

(B) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) Review records must be maintained for inspection by the department in accordance with subsection (mm) of this section.

(9) Security program.

(A) Applicability.

(i) Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this paragraph and paragraphs (10) - (17) of this subsection.

(ii) An applicant for a new license and each licensee that would become newly subject to the requirements of this paragraph and paragraphs (10) - (17) of this subsection upon application for modification of its license shall implement the requirements of this paragraph and paragraphs (10) - (17) of this subsection, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(iii) Any licensee that has not previously implemented the security orders or been subject to the provisions of this paragraph and paragraphs (10) - (17) of this subsection shall provide written notification to the department at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(B) General performance objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(C) Program features. Each licensee's security program must include the program features, as appropriate, described in paragraphs (10) - (16) of this subsection.

(10) General security program requirements.

(A) Security plan.

(i) Each licensee identified in paragraph (9)(A) of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection. The security plan must, at a minimum:

(I) describe the measures and strategies used to implement the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection; and

(II) identify the security resources, equipment, and technology used to satisfy the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection.

(ii) The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

(iii) A licensee shall revise its security plan as necessary to ensure the effective implementation of department and NRC requirements. The licensee shall ensure that:

(I) the revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(II) the affected individuals are instructed on the revised plan before the changes are implemented.

(iv) The licensee shall maintain a copy of the current security plan as a record for inspection by the department in accordance with subsection (mm) of this section. If any portion of the plan is superseded, the licensee shall maintain the superseded material for inspection by the department in accordance with subsection (mm) of this section.

(B) Implementing procedures.

(i) The licensee shall develop and maintain written procedures that document how the requirements of paragraph (9), this paragraph, and paragraphs (11) - (17) of this subsection and the security plan will be met.

(ii) The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

(iii) The licensee shall maintain a copy of the current procedure as a record for inspection by the department in accordance with subsection (mm) of this section. Superseded portions of the procedure shall be maintained for inspection by the department in accordance with subsection (mm) of this section.

(C) Training.

(i) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

(I) the licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(II) the responsibility to report promptly to the licensee any condition that causes or may cause a violation of the requirements of the department;

(III) the responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

(IV) the appropriate response to security alarms.

(ii) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

(iii) Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(I) review of the training requirements of this subparagraph of this paragraph and any changes made to the security program since the last training;

(II) reports on any relevant security issues, problems, and lessons learned;

(III) relevant results of inspections by the department; and

(IV) relevant results of the licensee's program review and testing and maintenance.

(iv) The licensee shall maintain records of the initial and refresher training for inspection by the department in accordance with subsection (mm) of this section. The training records shall include:

(I) the dates of the training;

(II) the topics covered;

(III) a list of licensee personnel in attendance; and

(IV) any related information.

(D) Protection of information.

(i) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

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

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

(I) evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

(II) if the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in paragraph (4)(A)(ii) - (vii) of this subsection.

(iv) Licensees need not subject the following individuals to the background investigation elements for protection of information:

(I) the categories of individuals listed in paragraph (6)(A)(i) - (xiii) of this subsection; or

(II) security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in paragraph (4)(A)(ii) - (vii) of this subsection, has been provided by the security service provider.

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

(vi) Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall:

(I) remove the person from the approved list as soon as possible, but no later than 7 working days; and

(II) take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

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

(viii) The licensee shall make, maintain, and retain as a record for inspection by the department in accordance with subsection (mm) of this section:

(I) a copy of the information protection procedures; and

(II) the list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

(11) LLEA coordination.

(A) A licensee subject to paragraphs (9) and (10), this paragraph, and paragraphs (12) - (17) of this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

(i) a description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with paragraphs (9) and (10), this paragraph, and paragraphs (12) - (17) of this subsection; and

(ii) a notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

(B) The licensee shall notify the department within three business days if:

(i) the LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(ii) the LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(C) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for inspection by the department in accordance with subsection (mm) of this section.

(D) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

(12) Security zones.

(A) Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

(B) Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(C) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

(i) isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

(ii) direct control of the security zone by approved individuals at all times; or

(iii) a combination of continuous physical barriers and direct control.

(D) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(E) Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

(13) Monitoring, detection and assessment.

(A) Monitoring and detection.

(i) Licensees shall:

(I) establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones;

(II) provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source; or

(III) provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(ii) Monitoring and detection must be performed by:

(I) a monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(II) electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(III) a monitored video surveillance system;

(IV) direct visual surveillance by approved individuals located within the security zone; or

(V) direct visual surveillance by a licensee designated individual located outside the security zone.

(iii) A licensee subject to paragraphs (9) - (12), this paragraph, and paragraphs (14) - (17) of this subsection shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(I) for category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(-a-) electronic sensors linked to an alarm;

(-b-) continuous monitored video surveillance; or

(-c-) direct visual surveillance; and

(II) for category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(B) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(C) Personnel communications and data transmission. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

(i) maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(ii) provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

(D) Response. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

(14) Maintenance and testing.

(A) Each licensee subject to paragraphs (9) - (13), this paragraph, and paragraphs (15) - (17) of this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(B) The licensee shall maintain records on the maintenance and testing activities for inspection by the department in accordance with subsection (mm) of this section.

(15) Requirements for mobile devices. Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material shall:

(A) have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

(B) for devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

(16) Security program review.

(A) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of paragraphs (9) - (15), this paragraph, and paragraph (17) of this subsection, and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. Each licensee shall review the security program content and implementation at least every 12 months.

(B) The results of the review, along with any recommendations, must be documented.

(i) Each review report must

(I) identify conditions that are adverse to the proper performance of the security program;

(II) identify the cause of the condition(s); and

(III) when applicable, recommend corrective actions, and identify and document any corrective actions taken.

(ii) The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) The licensee shall make, maintain, and retain the documentation of the review required under subparagraph (B) of this paragraph for inspection by the department in accordance with subsection (mm) of this section.

(17) Reporting of events.

(A) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the department at (512) 458-7460. In no case shall the notification to the department be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(B) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the department at (512) 458-7460.

(C) Each initial telephonic notification required by subparagraphs (A) and (B) of this paragraph must be followed within a period of 30 days by a written report submitted to the department. The report must include sufficient information for department analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

(18) Additional requirements for transfer of category 1 and category 2 quantities of radioactive material. A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the department, the NRC, or any agreement state shall meet the license verification requirements listed below instead of those listed in subsection (cc)(4) of this section.

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the department, the NRC, or any agreement state, before conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(B) Any licensee transferring category 2 quantities of radioactive material to a licensee of the department, the NRC, or any agreement state, before conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(C) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred.

(i) The certification must include:

(I) the license number;

(II) the current revision number;

(III) the issuing authority;

(IV) the expiration date; and

(V) for a category 1 shipment, the authorized address.

(ii) The licensee shall keep a copy of the certification.

(iii) The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(D) The transferor shall keep a copy of the verification documentation required under this paragraph as a record for inspection by the department in accordance with subsection (mm) of this section.

(19) Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit. The shipping licensee shall be responsible for meeting the requirements of paragraph (18), this paragraph, and paragraphs (20) - (23) of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this paragraph, and paragraphs (20) - (23) of this subsection.

(20) Preplanning and coordination of shipment of category 1 and category 2 quantities of radioactive material.

(A) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(i) preplan and coordinate shipment arrival and departure times with the receiving licensee;

(ii) preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to:

(I) discuss the state's intention to provide law enforcement escorts; and

(II) identify safe havens; and

(iii) document the preplanning and coordination activities.

(B) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(C) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(D) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subparagraph (B) of this paragraph, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall make, maintain, and retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for inspection by the department in accordance with subsection (mm) of this section.

(21) Advance notification of shipment of category 1 quantities of radioactive material. As specified in subparagraphs (A) and (B) of this paragraph, for shipments initially made by an agreement state licensee, each licensee shall provide advance notification to the Texas Department of Public Safety and the governor of the State of Texas, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for submitting advance notification.

(i) The notification must be made to the Texas Department of Public Safety and to the office of each appropriate governor or governor's designee.

(I) The contact information, including telephone and mailing addresses, of governors and governors’ designees, is available on the NRC’s Web site at https://scp.nrc.gov/special/designee.pdf. A list of agreement state advance notification contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(II) Notifications to the Texas Department of Public Safety must be to the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(iii) A notification delivered by any means other than mail must reach the Texas Department of Public Safety at least four days before the transport of the shipment commences; and

(iv) A notification delivered by any means other than mail must reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

(B) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(i) the name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(ii) the license numbers of the shipper and receiver;

(iii) a description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(iv) the point of origin of the shipment and the estimated time and date that shipment will commence;

(v) the estimated time and date that the shipment is expected to enter each state along the route;

(vi) the estimated time and date of arrival of the shipment at the destination; and

(vii) a point of contact, with a telephone number, for current shipment information.

(C) Revision notice.

(i) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) A licensee shall provide notice as follows of any changes to the information provided in accordance with subparagraphs (B) and (C)(i) of this paragraph.

(I) Promptly notify the governor of the state or the governor's designee.

(II) Immediately notify the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(D) Cancellation notice.

(i) Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to:

(I) the governor of each state or to the governor's designee previously notified; and

(II) the Director, Texas Department of Public Safety, Office of Homeland Security, P.O. Box 4087, Austin, Texas 78773 or by fax to (512) 424-5708.

(ii) The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible.

(iii) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(E) Records. The licensee shall make, maintain, and retain a copy of the advance notification and any revision and cancellation notices as a record for inspection by the department in accordance with subsection (mm) of this section.

(F) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the department, the NRC, or any agreement state, who receive schedule information of the kind specified in subparagraph (B) of this paragraph shall protect that information against unauthorized disclosure as specified in paragraph (10)(D) of this subsection.

(22) Requirements for physical protection of category 1 or category 2 quantities of radioactive material during shipment.

(A) Shipments by road.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies;

(II) ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(III) ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include the identification of and contact information for the appropriate LLEA along the shipment route;

(IV) provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(V) develop written normal and contingency procedures to address:

(-a-) notifications to the communication center and law enforcement agencies;

(-b-) communication protocols, which must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(-c-) loss of communications; and

(-d-) responses to an actual or attempted theft or diversion of a shipment.

(ii) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(iii) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(iv) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature before releasing the package for delivery or return.

(B) Shipments by rail.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include the identification of and contact information for the appropriate LLEA along the shipment route; and

(II) ensure that periodic reports to the communications center are made at preset intervals.

(ii) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature before releasing the package for delivery or return.

(C) Investigations.

(i) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing.

(ii) Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

(23) Reporting of events.

(A) The shipping licensee shall notify the appropriate LLEA and shall notify the department at (512) 458-7460 within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by paragraph (22)(C) of this subsection, the shipping licensee will provide agreed upon updates to the department on the status of the investigation.

(B) The shipping licensee shall notify the department at (512) 458-7460 within four hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the department.

(C) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the department at (512) 458-7460 upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(D) The shipping licensee shall notify the department at (512) 458-7460 as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(E) The shipping licensee shall notify the department at (512) 458-7460 and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(F) The shipping licensee shall notify the department at (512) 458-7460 as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by subparagraphs (A) - (D) of this paragraph must be followed within a period of 30 days by a written report submitted to the department. A written report is not required for notifications on suspicious activities required by subparagraphs (C) and (D) of this paragraph. The report must set forth the following information:

(i) a description of the licensed material involved, including kind, quantity, and chemical and physical form;

(ii) a description of the circumstances under which the loss or theft occurred;

(iii) a statement of disposition, or probable disposition, of the licensed material involved;

(iv) actions that have been taken, or will be taken, to recover the material; and

(v) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(H) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

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

(25) Record retention. All records/documents referenced in this subsection shall be made and maintained by the licensee for inspection by the department in accordance with subsection (mm) of this section. If a retention period is not otherwise specified, these records must be retained until the department terminates the facility's license. All records related to this subsection may be destroyed upon department termination of the facility license.

(jj) Appendices.

(1) Subjects to be included in training courses:

(A) fundamentals of radiation safety:

(i) characteristics of radiation;

(ii) units of radiation dose (rem) and activity of radioactivity (curie);

(iii) significance of radiation dose;

(I) radiation protection standards; and

(II) biological effects of radiation;

(iv) levels of radiation from sources of radiation;

(v) methods of controlling radiation dose;

(I) time;

(II) distance; and

(III) shielding;

(vi) radiation safety practices, including prevention of contamination and methods of decontamination; and

(vii) discussion of internal exposure pathways;

(B) radiation detection instrumentation to be used:

(i) radiation survey instruments:

(I) operation;

(II) calibration; and

(III) limitations;

(ii) survey techniques; and

(iii) individual monitoring devices;

(C) equipment to be used:

(i) handling equipment and remote handling tools;

(ii) sources of radiation;

(iii) storage, control, disposal, and transport of equipment and sources of radiation;

(iv) operation and control of equipment; and

(v) maintenance of equipment;

(D) the requirements of pertinent federal and state regulations;

(E) the licensee's written operating, safety, and emergency procedures; and

(F) the licensee's record keeping procedures.

(2) Isotope quantities (for use in subsection (gg) of this section).

Figure: 25 TAC §289.252(jj)(2)

(separate attachment - revised)

(3) Criteria relating to use of financial tests and parent company guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This paragraph establishes criteria for passing the financial test and for obtaining the parent company guarantee.

(B) Financial test.

(i) To pass the financial test, the parent company shall meet the criteria of either subclause (I) or (II) of this clause.

(I) The parent company shall have:

(-a-) two of the following three ratios:

(-1-) a ratio of total liabilities to net worth less than 2.0;

(-2-) a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and

(-3-) a ratio of current assets to current liabilities greater than 1.5;

(-b-) net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least $10 million; and

(-d-) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used.)

(II) The parent company shall have:

(-a-) a current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's;

(-b-) tangible net worth each at least six times the current decommissioning cost estimate for the total of all facilities or parts thereof (or prescribed amount if a certification is used);

(-c-) tangible net worth of at least $10 million; and

(-d-) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

(ii) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(iii) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(iv) If the parent company no longer meets the requirements of clause (i) of this subparagraph, the licensee shall send notice to the department of intent to establish alternate financial assurance as specified in the department’s regulations. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Parent company guarantee. The terms of a parent company guarantee that an applicant or licensee obtains shall provide that:

(i) the parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the department, as evidenced by the return receipts;

(ii) if the licensee fails to provide alternate financial assurance as specified in the department’s rules within 90 days after receipt by the licensee and the department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee;

(iii) the parent company guarantee and financial test provisions shall remain in effect until the department has terminated the license; and

(iv) if a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the department. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(4) Criteria relating to use of financial tests and self-guarantees for providing reasonable assurance of funds for decommissioning.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes a financial test of subparagraph (B) of this paragraph. Subparagraph (B) of this paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

(B) Financial test.

(i) To pass the financial test, a company shall meet all of the following criteria:

(I) tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor);

(II) assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor); and

(III) a current rating for its most recent bond issuance of AAA, AA, A as issued by Standard and Poor's, or Aaa, Aa, A as issued by Moody's.

(ii) To pass the financial test, a company shall meet all of the following additional criteria:

(I) the company shall have at least one class of equity securities registered under the Securities Exchange Act of 1934;

(II) the company's independent certified public accountant shall have compared the data used by the company in the financial test that is derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test; and

(III) after the initial financial test, the company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(iii) If the licensee no longer meets the criteria of clause (i) of this subparagraph, the licensee shall send immediate notice to the department of its intent to establish alternate financial assurance as specified in the department’s rules within 120 days of such notice.

(C) Company self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide that:

(i) the company guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the department, as evidenced by the return receipt.

(ii) the licensee shall provide alternate financial assurance as specified in the department’s rules within 90 days following receipt by the department of a notice of cancellation of the guarantee;

(iii) the guarantee and financial test provisions shall remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee;

(iv) the licensee will promptly forward to the department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission in accordance with the requirements of the Securities and Exchange Act of 1934, §13;

(v) if, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the department within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the criteria of subparagraph (B)(i) of this paragraph; and

(vi) the applicant or licensee shall provide to the department a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(5) Criteria relating to use of financial tests and self-guarantees for providing reasonable assurance of funds for decommissioning by commercial companies that have no outstanding rated bonds.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of subparagraph (B) of this paragraph. The terms of the self-guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

(B) Financial test.

(i) To pass the financial test a company shall meet the following criteria:

(I) tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(II) assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(III) a ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(ii) In addition, to pass the financial test, a company shall meet all of the following requirements:

(I) the company's independent certified public accountant shall have compared the data used by the company in the financial test, that is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the department within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test;

(II) after the initial financial test, the company shall repeat passage of the test within 90 days after the close of each succeeding fiscal year; and

(III) if the licensee no longer meets the requirements of subparagraph (B)(i) of this paragraph, the licensee shall send notice to the department of its intent to establish alternative financial assurance as specified in the department’s rules. The notice shall be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternative financial assurance within 120 days after the end of such fiscal year.

(C) Company self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following.

(i) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the department. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(ii) The licensee shall provide alternative financial assurance as specified in the department’s rules within 90 days following receipt by the department of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the department a written guarantee (a written commitment by a corporate officer) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(6) Criteria relating to use of financial tests and self-guarantees for providing reasonable assurance of funds for decommissioning by nonprofit entities, such as colleges, universities, and nonprofit hospitals.

(A) Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of subparagraph (B) of this paragraph. The terms of the self-guarantee are in subparagraph (C) of this paragraph. This paragraph establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee

(B) Financial test.

(i) To pass the financial test, a college or university shall meet the criteria of subclause (I) or (II) of this clause. The college or university shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) for applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(ii) To pass the financial test, a hospital shall meet the criteria in subclause (I) or (II) of this clause. The hospital shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) for applicants or licensees that do not issue bonds, all the following tests shall be met:

(-a-) (total revenues less total expenditures) divided by total revenues shall be equal to or greater than 0.04;

(-b-) long term debt divided by net fixed assets shall be less than or equal to 0.67;

(-c-) (current assets and depreciation fund) divided by current liabilities shall be greater than or equal to 2.55; and

(-d-) operating revenues shall be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

(iii) In addition, to pass the financial test, a licensee shall meet all the following requirements:

(I) the licensee's independent certified public accountant shall have compared the data used by the licensee in the financial test that is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test; and

(II) after the initial financial test, the licensee shall repeat passage of the test within 90 days after the close of each succeeding fiscal year;

(III) if the licensee no longer meets the requirements of subparagraph (A) of this paragraph, the licensee shall send notice to the department of its intent to establish alternative financial assurance as specified in the department’s rules. The notice shall be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(C) Self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following:

(i) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the department. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(ii) The licensee shall provide alternative financial assurance as specified in the department’s regulations within 90 days following receipt by the department of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the department a written guarantee (a written commitment by a corporate officer or officer of the institution) that states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(v) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of the fact to the department within 20 days after publication of the change by the rating service.

(7) Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release. The following table contains quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Figure: 25 TAC §289.252(jj)(7)

(separate attachment – no change)

(8) Requirements for demonstrating financial qualifications.

(A) If an applicant or licensee is not required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall demonstrate financial qualification by submitting attestation that the applicant or licensee is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the department issues a license.

(B) If an applicant or licensee is required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall:

(i) submit one of the following:

(I) the bonding company report or equivalent (from which information can be obtained to calculate a ratio in clause (ii) of this subparagraph) that was used to obtain the financial assurance instrument used to meet the financial assurance requirement specified in subsection (gg) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial assurance specified in subsection (gg) of this section, the applicant or licensee shall demonstrate financial qualification by one of the methods specified in subclause (II) or (III) of this clause;

(II) Securities and Exchange Commission documentation (from which information can be obtained to calculate a ratio as described in clause (ii) of this subparagraph, if the applicant or licensee is a publicly-held company); or

(III) a self-test (for example, an annual audit report certifying a company's assets and liabilities and resulting ratio as described in clause (ii) of this subparagraph or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues); and

(ii) declare its Standard Industry Classification (SIC) code. Several companies publish lists, on an annual basis, of acceptable assets-to liabilities (assets divided by liabilities) ratio ranges for each type of SIC code. If an applicant or licensee submits documentation of its current assets and current liabilities or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues, and the resulting ratio falls within an acceptable range as published by generally recognized companies (for example, Almanac of Business and Industrial Financial Ratios, Industry NORM and Key Business Ratios, Dun & Bradstreet Industry publications, and Manufacturing USA: Industry Analyses, Statistics, and Leading Companies), the department will consider that applicant or licensee financially qualified to conduct the requested or licensed activity.

(C) If the applicant or licensee is a state or local government entity, a statement of such will suffice as demonstration that the government entity is financially qualified to conduct the requested or licensed activities.

(D) The department will consider other types of documentation if that documentation provides an equivalent measure of assurance of the applicant's or licensee's financial qualifications as found in subparagraphs (A) and (B) of this paragraph.

(9) Category 1 and category 2 radioactive materials. Licensees shall use Figure: 25 TAC §289.252(jj)(9) to determine whether a quantity of radioactive material constitutes a Category 1 or Category 2 quantity of radioactive material.

Figure: 25 TAC §289.252(jj)(9)

(separate attachment – no change)

(10) Broad scope license limits (for use in subsection (h) of this section).

Figure: 25 TAC §289.252(jj)(10)

(separate attachment - new)

(kk) Requirements for the issuance of specific licenses for a medical facility or educational institution to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium.

(1) A license application will be approved if the department determines that an application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use in accordance with §289.256 of this title includes:

(A) a request for authorization for the production of PET radionuclides or evidence of an existing license issued in accordance with this section, the NRC, or another agreement states requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(B) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in subsection (r)(1)(A) of this section;

(C) identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in subsection (r)(3)(B) of this section; and

(D) information identified in subsection (r)(1)(B) of this section on the PET drugs to be noncommercially transferred to members of its consortium.

(2) Authorization in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

(3) Each licensee authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(A) satisfy the labeling requirements in subsection (r)(1)(C) of this section for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(B) possess and use instrumentation meeting the requirements of §289.202(p)(3)(D) of this title to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in subsection (r)(2) of this section.

(4) A licensee that is a pharmacy authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(A) an authorized nuclear pharmacist that meets the requirements in subsection (r)(3)(B) of this section; or

(B) an individual under the supervision of an authorized nuclear pharmacist as specified in §289.256(s) of this title.

(5) A pharmacy, authorized in accordance with paragraph (1) of this subsection to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of subsection (r)(3)(E) of this section.

(ll) Specific licenses for installation, repair, or maintenance of devices containing sealed sources of radioactive material.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing persons to perform installation, repair, or maintenance of devices containing sealed source(s) including source exchanges will be issued if the department approves the information submitted by the applicant.

(2) Each installation, repair, or maintenance activity shall be documented and a record maintained for inspection by the department in accordance with subsection (mm) of this section. The record shall include the date, description of the service, initial survey results, and name(s) of the individual(s) who performed the work.

(3) Installation, repair, maintenance, or source exchange activities shall be performed by a specifically licensed person unless otherwise authorized in accordance with subsection (v) of this section.

(mm) Records/documents retention. Each licensee shall make, maintain, and retain at each authorized use site and for the time period set forth in the table, the records/documents described in the following table and in the referenced rule provision, and shall make them available to the department for inspection, upon reasonable notice.

Figure: 25 TAC §289.252(mm)

(separate attachment - revised)

§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 (jj) 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 (jj) 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 (jj) 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 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 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 (xxx) 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 paragraph (3)(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 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 (kk) 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, 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 Registryfor 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 (2) and (3) 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 perform full 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 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 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, 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 individuals 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)

(separate attachment – revised and moved from (www))

§289.257 Packaging and Transportation of Radioactive Material

(a) Purpose.

(1) This section establishes requirements for packaging, preparation for shipment, and transportation of radioactive material including radioactive waste.

(2) The packaging and transport of radioactive material are also 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), §289.251 of this title (relating to Exemptions, General Licenses, and General License Acknowledgements), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material) and to the regulations of other agencies (e.g., the United States Department of Transportation (DOT) and the United States Postal Service) having jurisdiction over means of transport. The requirements of this section are in addition to, and not in substitution for, other requirements.

(b) Scope.

(1) The requirements of this section apply to any licensee authorized by a specific or general license issued by the department to receive, possess, use, or transfer radioactive material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the department license, or transports that material on public highways. No provision of this section authorizes possession of radioactive material.

(2) Exemptions from the requirements for a license in subsection (c) of this section are specified in subsection (f) of this section. The general license in subsection (i) (1) of this section requires that a United States Nuclear Regulatory Commission (NRC) certificate of compliance or other package approval be issued for the package to be used in accordance with the general license. A licensee transporting radioactive material, or delivering radioactive material to a carrier for transport, shall comply with the operating control requirements of subsections (l) - (q) of this section; the quality assurance requirements of subsections (s) – (u) and (w) – (bb) of this section; and the general provisions of subsections (a) - (e) of this section, including DOT regulations referenced in subsection (e) of this section.

(c) Requirement for license. Except as authorized in a general or specific license issued by the department, or as exempted in accordance with this section, no licensee may transport radioactive material or deliver radioactive material to a carrier for transport.

(d) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, SI units shall be used.

(1) A1--The maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (ee) of this section.

(2) A2 --The maximum activity of radioactive material, other than special form, low specific activity (LSA) and surface contaminated object (SCO) material, permitted in a Type A package. This value is either listed in Table 257-3 of subsection (ee)(6) of this section, or may be derived in accordance with the procedure prescribed in subsection (ee) of this section.

(3) Carrier--A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(4) Certificate holder--A person who has been issued a certificate of compliance or other package approval by the department.

(5) Certificate of compliance--The certificate issued by the NRC that approves the design of a package for the transportation of radioactive materials.

(6) Chelating agent--Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

(7) Chemical description--A description of the principal chemical characteristics of low-level radioactive waste (LLRW).

(8) Consignee--The designated receiver of the shipment of low-level radioactive waste.

(9) Consignment--Each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

(10) Containment system--The assembly of components of the packaging intended to retain the radioactive material during transport.

(11) Contamination--The presence of a radioactive substance on a surface in quantities in excess of 0.4 becquerel per square centimeter (Bq/cm2) (10-5 microcurie per square centimeter (µCi/cm2)) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm2 (10-6 µCi/cm2) for all other alpha emitters.

(A) Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.

(B) Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport.

(12) Conveyance--For transport on:

(A) public highway or rail by transport vehicle or large freight container;

(B) water by vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(C) aircraft.

(13) Criticality Safety Index (CSI)--The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in subsection (i) of this section and Title 10, Code of Federal Regulations (CFR), §71.22, §71.23, and §71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

(14) Decontamination facility--A facility operating in accordance with an NRC, agreement state, or department license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for LLRW shipments.

(15) Deuterium--For the purposes of this section, this means deuterium and any deuterium compound, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

(16) Disposal container--A transport container principally used to confine LLRW during disposal operations at a land disposal facility (also see definition for high integrity container). Note that for some shipments, the disposal container may be the transport package.

(17) Environmental Protection Agency (EPA) identification number--The number received by a transporter following application to the administrator of EPA as required by Title 40, CFR, Part 263.

(18) Exclusive use--The sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

(19) Fissile material--The radionuclides plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition. Agency jurisdiction extends only to special nuclear material in quantities not sufficient to form a "critical mass" as defined in §289.201(b) of this title. Certain exclusions from fissile material controls are provided in subsection (h) of this section.

(20) Freight forwarder--A person or entity which holds itself out to the general public to provide transportation of property for compensation and in the ordinary course of its business:

(A) assembles and consolidates, or provides for assembling and consolidating, shipments and performs break-bulk and distribution operations of the shipments;

(B) assumes responsibility for the transportation from the place of receipt to the place of destination; and

(C) uses for any part of the transportation a rail, motor or water carrier subject to the jurisdiction of either the Federal Motor Carrier Safety Administration or the Surface Transportation Board.

(21) Generator--A licensee operating in accordance with an agency, NRC, or agreement state license who:

(A) is a waste generator as defined in this section; or

(B) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

(22) Graphite--For the purposes of this section, this means graphite with a boron equivalent content of less than 5 parts per million and density greater than 1.5 grams per cubic centimeter.

(23) High integrity container (HIC)--A container commonly designed to meet the structural stability requirements of Title 10, CFR, §61.56, and to meet DOT requirements for a Type A package.

(24) Indian Tribe --An Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. §479a.

(25) Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(i) discarded or unwanted and is not exempt by rule adopted in accordance with the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR, §61.55, or compatible rules adopted by the department or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10, CFR, or established by the department or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined in Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined in Title 10, CFR, §72.3;

(iii) byproduct material defined in the Act, Health and Safety Code, §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries (3.7 kilobecquerels) per gram (g).

(26) Low specific activity (LSA) material--Radioactive material with limited specific activity which is nonfissile or is excepted in accordance with subsection (h) of this section, and which satisfies the following descriptions and limits set forth in this section. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of the following three groups:

(A) LSA-I.

(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides; or

(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form; or

(iii) Radioactive material other than fissile material for which the A2 value is unlimited; or

(iv) Other radioactive material (e.g.: mill tailings, contaminated earth, concrete, rubble, other debris, and activated material) in which the radioactivity is distributed throughout, and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with subsection (ee) of this section.

(B) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (TBq/l) (20.0 curies per liter (Ci/l)); or

(ii) Other material in which the radioactivity is distributed throughout, and the average specific activity does not exceed 10-4 A2/g for solids and gases, and 10-5 A2/g for liquids.

(C) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of Title 10, CFR, §71.77 in which:

(i) the radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(ii) the radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even with a loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, will not exceed 0.1 A2; and

(iii) the estimated average specific activity of the solid, excluding any shielding material, does not exceed 2 x 10-3 A2/g.

(27) Low toxicity alpha emitters--Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(28) Maximum normal operating pressure--The maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in Title 10, CFR, §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(29) Natural thorium--Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(30) Normal form radioactive material--Radioactive material that has not been demonstrated to qualify as special form radioactive material.

(31) NRC Forms 540, 540A, 541, 541A, 542, and 542A--Official NRC forms referenced in subsection (ff) of this section which includes the information required by DOT in Title 49, CFR, Part 172. Licensees need not use originals of these forms as long as any substitute forms contain the equivalent information. Licensees may include additional information deemed relevant to the licensee's shipment of low-level radioactive waste. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) or equivalent documents may be completed, transmitted, and stored in electronic media. The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(32) Package--The packaging together with its radioactive contents as presented for transport.

(A) Fissile material package, Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package--A fissile material packaging together with its fissile material contents.

(B) Type A package--A Type A packaging together with its radioactive contents. A Type A package is defined and shall comply with the DOT regulations in Title 49, CFR, Part 173.

(C) Type B package--A Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascals (kPa) (100 pounds per square inch (lb/ in2)) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in Title 10, CFR, §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in Title 49, CFR, Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in Title 10, CFR, §71.19.

(33) Packaging--The assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(34) Physical description--The items called for on NRC Form 541 to describe a LLRW.

(35) Registered freight forwarder--A freight forwarder that has an emergency plan approved in accordance with subsection (r) of this section and has been issued a registration letter.

(36) Registered shipper--A shipper that has an emergency plan approved in accordance with subsection (r) of this section, and shipping containers approved in accordance with subsection(cc)(8) of this section and been issued a registration letter.

(37) Registered transporter--A transporter that has an emergency plan approved in accordance with subsection (r) of this section, and proof of financial responsibility submitted and approved in accordance with subsection(e)(4) of this section and has been issued a registration letter.

(38) Residual waste--LLRW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(39) Shipper--The licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers LLRW for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator. This definition applies only to shipments of LLRW shipped to a Texas LLRW disposal facility.

(40) Site of usage--The licensee's facility, including all buildings and structures between which radioactive material is transported and all roadways that are not within the public domain on which radioactive material can be transported.

(41) Special form radioactive material--Radioactive material that satisfies the following conditions:

(A) it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(B) the piece or capsule has at least one dimension not less than five millimeters (0.2 in); and

(C) it satisfies the requirements of Title 10, CFR, §71.75. A special form encapsulation designed in accordance with the requirements of this subsection in effect on or after June 30, 1983 (see Title 10, CFR, Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of this subsection in effect on or after March 31, 1996 (see Title 10, CFR, Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and

(D) special form material that was successfully tested before September 10, 2015, in accordance with the requirements of Title 10, CFR, §71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

(42) Specific activity of a radionuclide--The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(43) Spent nuclear fuel or spent fuel--Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(44) Surface contaminated object (SCO)--A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. A SCO shall be in one of the following two groups with surface activity not exceeding the following limits:

(A) SCO-I--A solid object on which:

(i) the non-fixed contamination on the accessible surface averaged over 300 square centimeters (cm2) (or the area of the surface if less than 300 cm2) does not exceed 4 becquerels per square centimeter (Bq/cm2) (10-4 microcurie per square centimeter (µCi/cm2)) for beta and gamma and low toxicity alpha emitters, or 4 x 10-1 Bq/cm2 (10-5 µCi/cm2) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4 x 104 Bq/ cm2 (1 µCi/ cm2) for beta and gamma and low toxicity alpha emitters, or 4 x 103 Bq/ cm2 (10-1 µCi/ cm2) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4 x 104 Bq/cm2 (1 µCi/ cm2) for beta and gamma and low toxicity alpha emitters, or 4 x 103 Bq/cm2 (10-1 µCi/cm2) for all other alpha emitters.

(B) SCO-II--A solid object on which the limits for SCO-I are exceeded and on which the following limits are not exceeded:

(i) the non-fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 400 Bq/cm2 (10-2 µCi/cm2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm2 (10-3 µCi/cm2) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 µCi/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 µCi/cm2) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 µCi/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/ cm2 (2 µCi/cm2) for all other alpha emitters.

(45) Transporter--A carrier who transports radioactive material.

(46) Tribal official--The highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(47) Uniform Low-Level Radioactive Waste Manifest or uniform manifest--The combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(48) Unirradiated uranium--Uranium containing not more than 2 x 103 Bq (0.054 µCi) of plutonium per gram of uranium-235, not more than 9 x 106 Bq (243 µCi) of fission products per gram of uranium-235, and not more than 5 x 10-3 g of uranium-236 per gram of uranium-235.

(49) Uranium--Natural, depleted, enriched:

(A) Natural uranium--Uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) Depleted uranium--Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) Enriched uranium--Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(50) Waste collector--An entity, operating in accordance with an agency, NRC, or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(51) Waste description--The physical, chemical and radiological description of a LLRW as called for on NRC Form 541.

(52) Waste generator--An entity, operating in accordance with an agency, NRC, or agreement state license, who:

(A) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(B) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment before disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of LLRW from its facility is defined as residual waste.

(53) Waste processor--An entity, operating in accordance with an NRC or agreement state license, whose principal purpose is to process, repackage, or otherwise treat LLRW or waste generated by others before eventual transfer of waste to a licensed LLRW land disposal facility.

(54) Waste type--A waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically-defined media).

(e) Transportation of radioactive material.

(1) Each licensee who transports radioactive material outside the site of usage as specified in the department license, transports on public highways, or delivers radioactive material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in Title 49, CFR, Part 107, Parts 171 - 180 and 390 - 397 appropriate to the mode of transport. The licensee shall particularly note DOT regulations in the following areas:

(A) Packaging - Title 49, CFR, Part 173: Subparts A, B, and I.

(B) Marking and labeling - Title 49, CFR, Part 172: Subpart D, and §§172.400 - 172.407 and §§172.436 - 172.441 of Subpart E.

(C) Placarding - Title 49, CFR, Part 172: Subpart F, especially §§172.500 - 172.519 and §172.556, and Appendices B and C.

(D) Accident reporting - Title 49, CFR, Part 171: §171.15 and §171.16.

(E) Shipping papers and emergency information - Title 49, CFR, Part 172: Subparts C and G.

(F) Hazardous material employee training - Title 49, CFR, Part 172: Subpart H.

(G) Hazardous material shipper/carrier registration - Title 49, CFR, Part 107: Subpart G.

(H) Security Plans - Title 49, CFR, Part 172: Subpart I.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:

(A) Rail: Title 49, CFR Part 174: Subparts A through D and K.

(B) Air: Title 49, CFR Part 175.

(C) Vessel: Title 49, CFR Part 176: Subparts A through F and M.

(D) Public Highway: Title 49, CFR Part 177 and Parts 390 through 397.

(3) If DOT regulations are not applicable to a shipment of radioactive material (i.e. DOT does not have jurisdiction), the licensee shall conform to DOT standards and requirements specified in paragraph (1) of this subsection to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements shall be filed and approved by the department. Any notification referred to in those requirements, shall be submitted to the department.

(4) Transporter proof of financial responsibility.

(A) Transporters of low-level radioactive waste to a Texas low-level radioactive waste disposal site shall submit proof of financial responsibility required by Title 49, CFR, §387.7 and §387.9, to the department and receive a registration letter from the department before initial shipment.

(B) The transporter registration expires on the expiration date of the proof of financial responsibility or in 10 years, if the proof of financial responsibility does not have an expiration date.

(C) To renew a transporter's registration, the transporter shall submit to the department new proof of financial responsibility.

(D) The transporter shall submit to the department new proof of financial responsibility any time the amount of liability coverage is reduced or a new policy is purchased.

(5) The department shall review and determine alternate routes for the transportation and routing of radioactive material in accordance with 49 CFR, §397.103.

(f) Exemption for low-level radioactive materials.

(1) A licensee is exempt from all requirements of this section with respect to shipment or carriage of the following low-level materials:

(A) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in subsection (ee), (ee)(7), and (ee)(8) of this section.

(B) Materials for which the activity concentration is not greater than the activity concentration values specified in subsection (ee), (ee)(7), and (ee)(8) of this section, or for which the consignment activity is not greater than the limit for an exempt consignment found in subsection (ee), (ee)(7), and (ee)(8) of this section.

(C) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in subsection (d) of this section.

(2) Common and contract carriers, freight forwarders, warehousemen, and the United States Postal Service are exempt from the regulations in this subchapter to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto.

(3) Persons who discard licensed material in accordance with §289.202(fff) of this title are exempt from all requirements of this section.

(g) Exemption of physicians. Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from subsection (e) of this section with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption shall be licensed in accordance with §289.256 of this title or the equivalent NRC or agreement state regulations.

(h) Exemption from classification as fissile material. Fissile materials meeting the requirements of at least one of the paragraphs (1) through (6) of this subsection are exempt from classification as fissile material and from the fissile material package standards of Title 10, CFR §71.55 and §71.59, but are subject to all other requirements of this section, except as noted.

(1) An individual package containing 2 grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass for solid nonfissile material.

(3) Solid fissile material commingled with solid non-fissile material.

(A) Low concentrations of solid fissile material commingled with solid nonfissile material provided:

(i) that there is at least 2000 grams of solid nonfissile material for every gram of fissile material; and

(ii) there is no more than 180 grams of fissile material distributed within 360 kg of contiguous non-fissile material.

(B) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but shall not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of one percent by weight, and with total plutonium and uranium-233 content of up to one percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material shall be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(i) General license.

(1) NRC-approved package.

(A) A general license is issued to any licensee of the department to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.

(B) This general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71, Subpart H.

(C) This general license applies only to a licensee who meets the following requirements:

(i) has a copy of the CoC or other approval by the NRC of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(ii) complies with the terms and conditions of the specific license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of Title 10, CFR, Part 71, Subparts A, G, and H; and

(iii) before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in Title 10, CFR, Part 71, the licensee's name and license number and the package identification number specified in the package approval.

(D) This general license applies only when the package approval authorizes use of the package in accordance with this general license.

(E) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of paragraph (2) of this subsection.

(F) For radiography containers, a program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m)(2)(B) of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), is deemed to satisfy the requirements of subparagraph (B) of this paragraph.

(2) Use of foreign approved package.

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of Title 49, CFR, §171.23.

(B) Except as otherwise provided by this section, the general license applies only to a licensee who has a quality assurance program approved by the department as satisfying the applicable provisions of subsection (s) – (u) and (w) – (bb) of this section.

(C) This general license applies only to shipments made to or from locations outside the United States.

(D) Each licensee issued a general license under subparagraph (A) of this paragraph shall:

(i) maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

(ii) comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of §289.205(j) and (k) of this title and subsections (a) – (e), (j) – (q), (s) – (u) and (w) - (bb) of this section.

(3) Fissile material.

(A) A general license is issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package that meets the standards of this section; however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of radioactive material; and

(ii) contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI that:

(i) has been determined in accordance with paragraph (E) of this subsection;

(ii) has a value less than or equal to 10.0; and

(iii) for a shipment of multiple packages containing fissile material, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on an exclusive use conveyance).

(E) The CSI shall be as follows:

(i) the value for the CSI shall be greater than or equal to the number calculated by the following equation:

Figure: 25 TAC §289.257(i)(3)(E)(i)

(separate attachment – moved from (i)(5)(E)(i))

(ii) the calculated CSI shall be rounded up to the first decimal place;

(iii) the values of X, Y, and Z used in the CSI equation shall be taken from Tables 257-1 or 257-2 of this clause, as appropriate;

Figure: 25 TAC §289.257(i)(3)(E)(iii)

(separate attachment – revised and moved from (i)(5)(E)(iii))

(iv) if Table 257-2 of clause (iii) of this subparagraph is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium shall be assumed to be zero; and

(v) Table 257-1 values of clause (iii) of this subparagraph for X, Y, and Z shall be used to determine the CSI if:

(I) uranium-233 is present in the package;

(II) the mass of plutonium exceeds one percent of the mass of uranium-235;

(III) the uranium is of unknown uranium-235 enrichment, or greater than 24 weight percent enrichment; or

(IV) substances having a moderating effectiveness (i.e. an average hydrogen density greater than H2 O) (e.g. certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

(4) Plutonium-beryllium special form material.

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package that meets the standards of Title 10, CFR, Part 71, however, the material shall be contained in a Type A package. The Type A package shall also meet the DOT requirements of Title 49, CFR, §173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the NRC as satisfying the provisions of Title 10, CFR, Part 71.

(C) The general license applies only when a package's contents:

(i) contain no more than a Type A quantity of material; and

(ii) contain less than 1000g of plutonium, provided that plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI that:

(i) has been determined in accordance with subparagraph (E) of this paragraph;

(ii) has a value less than or equal to 100.0; and

(iii) for a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs shall be less than or equal to 50.0 (for shipment on a nonexclusive use conveyance) and less than or equal to 100.0 (for shipment on or exclusive use conveyance).

(E) The value for the CSI shall be as follows:

(i) the CSI shall be greater than or equal to the number calculated by the following equation:

Figure: 25 TAC §289.257(i)(4)(E)(i)

(separate attachment – moved from (i)(6)(E)(i))

(ii) the calculated CSI shall be rounded up to the first decimal place.

(j) Assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(k) Preliminary determinations. Before the first use of any packaging for the shipment of licensed material the licensee shall

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ascertain that the determinations have been made in accordance with Title 10, CFR, §71.85.

(l) Routine determinations. Before each shipment of radioactive material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this section and of the license. The licensee shall determine that:

(1) the package is proper for the contents to be shipped;

(2) the package is in unimpaired physical condition except for superficial defects such as marks or dents;

(3) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;

(4) any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(5) any pressure relief device is operable and set in accordance with written procedures;

(6) the package has been loaded and closed in accordance with written procedures;

(7) for fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(8) any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of Title 10, CFR, §71.45;

(9) the level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable (ALARA), and within the limits specified in DOT regulations in Title 49, CFR, §173.443;

(10) external radiation levels around the package and around the vehicle, if applicable, will not exceed the following limits at any time during transportation:

(A) Except as provided in subparagraph (B) of this paragraph, each package of radioactive materials offered for transportation shall be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/hr (200 mrem/hr) at any point on the external surface of the package, and the transport index does not exceed 10.

(B) A package that exceeds the radiation level limits specified in subparagraph (A) of this paragraph shall be transported by exclusive use shipment only, and the radiation levels for such shipment shall not exceed the following during transportation:

(i) 2 mSv/hr (200 mrem/hr) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/hr (1,000 mrem/hr):

(I) the shipment is made in a closed transport vehicle;

(II) the package is secured within the vehicle so that its position remains fixed during transportation; and

(III) there are no loading or unloading operations between the beginning and end of the transportation;

(ii) 2 mSv/hr (200 mrem/hr) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(iii) 0.1 mSv/hr (10 mrem/hr) at any point 2 meters (m) (6.6 feet (ft)) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 m (6.6 ft) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(iv) 0.02 mSv/hr (2 mrem/hr) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with §289.202(q) of this title.

(C) For shipments made in accordance with the provisions of subparagraph (B) of this paragraph, the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions shall be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments shall be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

(m) Air transport of plutonium.

(1) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this section or included indirectly by citation of Title 49, CFR, Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

(A) the plutonium is contained in a medical device designed for individual human application; or

(B) the plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table 257-4 of subsection (ee)(7) of this section, and in which the radioactivity is essentially uniformly distributed; or

(C) the plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form, and is shipped in accordance with subsection (e) of this section; or

(D) the plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

(2) Nothing in paragraph (1) of this subsection is to be interpreted as removing or diminishing the requirements of Title 10, CFR, §73.24.

(3) For a shipment of plutonium by air which is subject to paragraph (1) of this subsection, the licensee shall, through special arrangement with the carrier, require compliance with Title 49, CFR, §175.704, DOT regulations applicable to the air transport of plutonium.

(n) Opening instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with §289.202(ee)(5) of this title.

(o) Records.

(1) For a period of three years after shipment, each licensee shall maintain, for inspection by the department, a record of each shipment of radioactive material not exempt under subsection (f) of this section,including the following where applicable:

(A) identification of the packaging by model number and serial number;

(B) verification that there are no significant defects in the packaging, as shipped;

(C) volume and identification of coolant;

(D) type and quantity of radioactive material in each package, and the total quantity of each shipment;

(E) for each item of irradiated fissile material:

(i) identification by model number and serial number;

(ii) irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) any abnormal or unusual condition relevant to radiation safety;

(F) date of the shipment;

(G) for fissile packages and for Type B packages, any special controls exercised;

(H) name and address of the transferee;

(I) address to which the shipment was made; and

(J) results of the determinations required by subsection (l) of this section and by the conditions of the package approval.

(2) The licensee, certificate holder, and an applicant for a CoC, shall make available to the department for inspection, upon reasonable notice, all records required by this section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(3) The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging.

(A) The records to be maintained include:

(i) results of the determinations required by subsection (k) of this section;

(ii) design, fabrication, and assembly records;

(iii) results of reviews, inspections, tests, and audits;

(iv) results of monitoring work performance and materials analyses; and

(v) results of maintenance, modification, and repair activities.

(B) Inspection, test, and audit records must identify the:

(i) inspector or data recorder;

(ii) type of observation;

(iii) results;

(iv) acceptability; and

(v) action taken in connection with any deficiencies noted.

(C) These records must be retained for three years after the life of the packaging to which they apply.

(p) Reports. The transporter and shipper shall immediately report by telephone all radioactive waste transportation accidents to the department, at (512) 458-7460, and the local emergency management officials in the county where the radioactive waste accident occurs. All other accidents involving radioactive material shall be reported in accordance with §289.202(xx) and (yy) of this title.

(q) Advance notification of transport of irradiated reactor fuel and certain radioactive waste.

(1) As specified in paragraphs (3) - (5) of this subsection, each licensee shall provide advance notification to the governor of a state, or the governor's designee, of the shipment of radioactive waste, within or across the boundary of the state, before the transport, or delivery to a carrier, for transport, of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(2) As specified in paragraphs (3) - (5) of this subsection, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (4)(C)(iii) of this subsection, or the official's designee, of the shipment of radioactive waste, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of radioactive waste outside the confines of the licensee's facility or other place of use or storage.

(3) Advanced notification is also required under this subsection for the shipment of licensed radioactive material, other than irradiated fuel, meeting the following three conditions:

(A) the radioactive waste is required by this section to be in Type B packaging for transportation;

(B) the radioactive waste is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

(C) the quantity of radioactive waste in a single package exceeds the least of the following:

(i) 3,000 times the A1 value of the radionuclides as specified in subsection (ee) of this section for special form radioactive material;

(ii) 3,000 times the A2 value of the radionuclides as specified in subsection (ee) of this section for normal form radioactive material; or

(iii) 1,000 terabecquerels (TBq) (27,000 curies (Ci)).

(4) The following are procedures for submitting advance notification:

(A) The notification shall be made in writing to:

(i) the office of each appropriate governor or governor's designee and to the department;

(ii) the office of each appropriate Tribal official or Tribal official's designee; and

(iii) the Director, Office of Nuclear Security and Incident Response.

(B) A notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(C) A notification delivered by any other means than mail shall reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of radioactive waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

(ii) Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) The licensee shall retain a copy of the notification for inspection by the department as a record for three years.

(5) Each advance notification of shipment of irradiated reactor fuel or radioactive waste shall contain the following information:

(A) the name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or radioactive waste shipment;

(B) a description of the irradiated reactor fuel or radioactive waste contained in the shipment, as specified in the regulations of DOT in Title 49, CFR, §172.202 and §172.203(d);

(C) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(D) the seven-day period during which arrival of the shipment at state boundaries or Tribal reservation is estimated to occur;

(E) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(F) a point of contact, with a telephone number, for current shipment information.

(6) A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the state or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(7) The following are procedures for a cancellation notice.

(A) Each licensee who cancels an irradiated reactor fuel or radioactive waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Director, Office of Nuclear Security and Incident Response, and to the department.

(B) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

(r) Emergency plan registration requirements.

(1) Each shipper and transporter of radioactive waste shall submit an emergency plan to the department and receive a registration letter from the department before to initial shipment.

(2) A freight forwarder must submit an emergency plan in order to become a registered freight forwarder.

(3) Each shipper, transporter or freight forwarder applying for registration shall submit a Business Information Form (RC 252-1).

(4) Shipper and freight forwarder registrations expire 10 years from the date of issuance. New documentation to renew the registration must be submitted at least 30 days before the expiration date.

(s) Quality assurance requirements.

(1) Purpose. This subsection describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

(A) Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

(B) Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(C) The licensee, certificate holder, and applicant for a CoC are responsible for the following:

(i) the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging; and

(ii) the quality assurance provision applicable to its use of a packaging for the shipment of licensed material under subsections (s) - (bb) and (ee) of this section.

(2) Establishment of program. Each licensee, certificate holder, and applicant for a CoC shall:

(A) Establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subsection, subsections (s) and (t) of this section and Title 10, CFR, §§71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging; and

(B) Execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(3) Approval of program. Before the use of any package for the shipment of licensed material subject to this subsection, each licensee shall:

(A) obtain department approval of its quality assurance program; and

(B) file a description of its quality assurance program, including a discussion of which requirements of this subsection and subsections (t) and (u) are applicable and how they will be satisfied.

(4) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of §289.255(m) of this title, is deemed to satisfy the requirements of subsection (i)(1)(B) of this section and paragraph (2) of this subsection.

(t) Quality assurance organization. The licensee, certificate holder, and applicant for a CoC shall (while the term "licensee" is used in these criteria, the requirements are applicable to whatever design, fabricating, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued):

(1) be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program; and

(2) clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(3) establish quality assurance functions as follows:

(A) assuring that an appropriate quality assurance program is established and effectively executed; and

(B) verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(4) assure that persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to:

(A) identify quality problems;

(B) initiate, recommend, or provide solutions; and

(C) verify implementation of solutions.

(u) Quality assurance program. A quality assurance program shall be maintained as follows:

(1) The licensee, certificate holder, and applicant for a CoC shall:

(A) establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of this section and Title 10, CFR, §§71.101 through 71.137;

(B) document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used; and

(C) identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall:

(A) provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material;

(B) assure that activities affecting quality are accomplished under suitable controlled conditions which include:

(i) the use of appropriate equipment;

(ii) suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and

(iii) all prerequisites for the given activity have been satisfied; and

(C) take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(3) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components.

(A) The impact of malfunction or failure of the item to safety;

(B) The design and fabrication complexity or uniqueness of the item;

(C) The need for special controls and surveillance over processes and equipment;

(D) The degree to which functional compliance can be demonstrated by inspection or test; and

(E) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.

(5) The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

(6) Changes to quality assurance program.

(A) Each quality assurance program approval holder shall submit, in accordance with §289.201(k) of this title, a description of a proposed change to its agency-approved quality assurance program that will reduce commitments in the program description as approved by the department. The quality assurance program approval holder shall not implement the change before receiving agency approval. The description of a proposed change to the agency-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subsections (s) - (bb) of this section.

(B) Each quality assurance program approval holder may change a previously approved quality assurance program without prior agency approval, if the change does not reduce the commitments in the quality assurance program previously approved by the department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the department every 24 months in accordance with §289.201(k) of this title. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(i) the use of a quality assurance standard approved by the department that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;

(ii) the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(iii) the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(iv) the elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(v) organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(C) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

(v) Quality control program. Each shipper shall adopt a quality control program to include verification of the following to ensure that shipping containers are suitable for shipments to a licensed disposal facility:

(1) identification of appropriate container(s);

(2) container testing documentation is adequate;

(3) appropriate container used;

(4) container packaged appropriately;

(5) container labeled appropriately;

(6) manifest filled out appropriately; and

(7) documentation maintained of each step.

(w) Handling, storage, and shipping control. The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels shall be specified and provided.

(x) Inspection, test, and operating status. Measures to track inspection, test and operating status shall be established as follows.

(1) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures shall provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests; and

(2) The licensee, shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

(y) Nonconforming materials, parts, or components. The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures shall include the following, as appropriate:

(1) procedures for identification, documentation, segregation, disposition, and notification to affected organizations; and

(2) nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

(z) Corrective action. The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected.

(1) In the case of a significant condition adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.

(2) The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

(aa) Quality assurance records. The licensee, certificate holder, and applicant for a CoC shall maintain written records sufficient to describe the activities affecting quality for inspection by the department for three years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for three years after it is superseded. The records must include the following:

(1) instructions, procedures, and drawings to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment;

(2) instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility; and

(3) changes to the quality assurance program as required by subsection (u)(6) of this section.

(bb) Audits. The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program. The audit program shall include:

(1) performance in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited;

(2) documented results that are reviewed by management having responsibility in the area audited; and

(3) follow-up action, including reaudit of deficient areas, shall be taken where indicated.

(cc) Transfer for disposal and manifests.

(1) The requirements of this section and subsection (ff) of this section are designed to:

(A) control transfers of LLRW by any waste generator, waste collector, or waste processor licensee, as defined in this section, who ships LLRW either directly, or indirectly through a waste collector or waste processor, to a licensed LLRW land disposal facility, as defined in §289.201(b) of this title;

(B) establish a manifest tracking system; and

(C) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(2) Beginning March 1, 1998, all affected licensees shall use subsection (ff) of this section.

(3) Each shipment of LLRW intended for disposal at a licensed land disposal facility shall be accompanied by a shipment manifest in accordance with subsection (ff)(1) of this section.

(4) Any licensee shipping LLRW intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform manifest and transfer this recorded manifest information to the intended consignee in accordance with subsection (ff) of this section.

(5) Each shipment manifest shall include a certification by the waste generator as specified in subsection (ff)(10) of this section, as appropriate.

(6) Each person involved in the transfer for disposal and disposal of LLRW, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in subsection (ff) of this section, as appropriate.

(7) Any licensee shipping LLRW to a licensed Texas LLRW disposal facility shall comply with the waste acceptance criteria in Title 30, Texas Administrative Code, Part 1, Chapter 336.

(8) Each shipper shall submit a list for approval by the department of shipping containers that they intend to use to ship LLRW to the Texas LLRW site. If the shipper is licensed in Texas and is the holder of a CoC, the shipper shall also submit written documentation of its program for quality assurance and control and handling, shipping and control measures that comply with the requirements of subsections (s), (t), and (v) - (bb) of this section.

(dd) Fees.

(1) Each shipper shall be assessed a fee for shipments of LLRW originating in Texas or originating out-of-state being shipped to a licensed Texas LLRW disposal facility and these fees shall:

(A) be $10 per cubic foot of shipped LLRW;

(B) be collected by the department and deposited to the credit of the department’s Radiation and Perpetual Care Account;

(C) be used by the department for emergency planning for and response to transportation accidents involving LLRW, including first responder training in counties through which transportation routes are designated in accordance with this section; and

(D) not be collected on waste disposed of at a federal waste disposal facility.

(2) Fee assessments are suspended from imposition against a party state compact waste generator when the amount in the department’s Radiation and Perpetual Care Account attributable to those fees reaches $500,000. If the amount in that account attributable to those fees is reduced to $350,000 or less, the fee is reinstated until the amount reaches $500,000.

(3) Money expended from the department’s Radiation and Perpetual Care Account to respond to accidents involving LLRW shall be reimbursed to the department’s Radiation and Perpetual Care Account by the responsible shipper or transporter according to this section.

(4) For purposes of this subsection, "shipper" means a person who generates low-level radioactive waste and ships or arranges with others to ship the waste to a disposal site.

(5) This subsection does not relieve a generator from liability for a transportation accident involving LLRW.

(ee) Appendices for determination of A1 and A2.

(1) Values of A1 and A2. Values of A1 and A2 for individual radionuclides, which are the bases for many activity limits elsewhere in these rules are given in Table 257-3 of paragraph (6) of this subsection. The curie (Ci) values specified are obtained by converting from the terabecquerel (TBq) value. The TBq values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A1 or A2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

(2) Values of radionuclides not listed.

(A) For individual radionuclides whose identities are known, but are not listed in Table 257-3 of paragraph (6) of this subsection, the A1 and A2 values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior department or NRC approval of the A1 and A2 values for radionuclides not listed in Table 257-3 of paragraph (6) of this subsection, before shipping the material.

(B) For individual radionuclides whose identities are known, but that are not listed in Table 257-4 of paragraph (7) of this subsection, the exempt material activity concentration and exempt consignment activity values contained in Table 257-5 of paragraph (8) of this subsection may be used. Otherwise, the licensee shall obtain prior department or NRC approval of the exempt material activity concentration and exempt consignment activity values, for radionuclides not listed in Table 257-4 of paragraph (7) of this subsection, before shipping the material.

(C) The licensee shall submit requests for prior approval, described in subparagraphs (A) and (B) of this paragraph to the department or the NRC.

(3) Calculations of A1 and A2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection. In the calculations of A1 and A2 for a radionuclide not in Table 257-3 of paragraph (6) of this subsection, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account and the A1 and A2 value to be applied shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

(4) Determination for mixtures of radionuclides whose identities and respective activities are known. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply.

(A) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

Figure: 25 TAC §289.257(ee)(4)(A)

(separate attachment – no change)

(B) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

Figure: 25 TAC §289.257(ee)(4)(B)

(separate attachment – no change)

(C) If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

Figure: 25 TAC §289.257(ee)(4)(C)

(separate attachment – no change)

(D) Alternatively, an A1 value for mixtures of special form material may be determined as follows:

Figure: 25 TAC §289.257(ee)(4)(D)

(separate attachment – no change)

(E) Alternatively, an A2 value for mixtures of normal form material may be determined as follows:

Figure: 25 TAC §289.257(ee)(4)(E)

(separate attachment – no change)

(F) The exempt activity concentration for mixtures of nuclides may be determined as follows:

Figure: 25 TAC §289.257(ee)(4)(F)

(separate attachment – no change)

(G) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

Figure: 25 TAC §289.257(ee)(4)(G)

(separate attachment – no change)

(5) Determination when individual activities of some of the radionuclides are not known.

(A) When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A1 or A2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A1 or A2 values for the alpha emitters and beta/gamma emitters.

(B) When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph (4) of this subsection. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A or A values for the alpha emitters and beta/gamma emitters, respectively.

(6) A1 and A2 values for radionuclides. The following Table 257-3 contains A1 and A2 values for radionuclides.

Figure: 25 TAC §289.257(ee)(6)

(separate attachment – no change)

(7) Exempt material activity concentrations and exempt consignment activity limits for radionuclides. The following Table 257-4 contains exempt material activity concentrations and exempt consignment activity limits for radionuclides:

Figure: 25 TAC §289.257(ee)(7)

(separate attachment – no change)

(8) General values for A1 and A2. The following Table 257-5 contains general values for A1 and A2:

Figure: 25 TAC §289.257(ee)(8)

(separate attachment – no change)

(9) Activity-mass relationships for uranium. The following Table 257-6 contains activity-mass relationships for uranium:

Figure: 25 TAC §289.257(ee)(9)

(separate attachment – no change)

(ff) Appendices for the requirements for transfers of LLRW intended for disposal at licensed land disposal facilities and manifests.

(1) Manifest. A waste generator, collector, or processor who transports, or offers for transportation, LLRW intended for ultimate disposal at a licensed LLRW land disposal facility shall prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)) or their equivalent. NRC Forms 540 and 540A shall be completed and shall physically accompany the pertinent LLRW shipment. Upon agreement between shipper and consignee, NRC Forms 541, 541A, and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the department to comply with the manifesting requirements of this section when they ship:

(A) LLRW for processing and expect its return (i.e., for storage in accordance with their license) before disposal at a licensed land disposal facility;

(B) LLRW that is being returned to the licensee who is the waste generator or generator, as defined in this section; or

(C) radioactively contaminated material to a waste processor that becomes the processor's residual waste.

(2) Form instructions. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this subsection may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

(3) Forms. NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-5877; or by visiting the NRC's Web site at http://www.nrc.gov and selecting forms from the index found on the NRC home page or at www.nrc.gov/reading-rm/doc-collections/forms/#NRC.

(4) Information requirements of the DOT. This subsection includes information requirements of the DOT, as codified in Title 49, CFR, Part 172. Information on hazardous, medical, or other waste, required to meet EPA regulations, as codified in Title 40, CFR, Parts 259 and 261 or elsewhere, is not addressed in this section, and shall be provided on the required EPA forms. However, the required EPA forms shall accompany the uniform manifest required by this section.

(5) General information. The shipper of the LLRW, shall provide the following information on the uniform manifest:

(A) the name, facility address, and telephone number of the licensee shipping the waste;

(B) an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(C) the name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

(6) Shipment information. The shipper of the LLRW shall provide the following information regarding the waste shipment on the uniform manifest:

(A) the date of the waste shipment;

(B) the total number of packages/disposal containers;

(C) the total disposal volume and disposal weight in the shipment;

(D) the total radionuclide activity in the shipment;

(E) the activity of each of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 contained in the shipment; and

(F) the total masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(7) Disposal container and waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(A) an alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(B) a physical description of the disposal container, including the manufacturer and model of any high integrity container;

(C) the volume displaced by the disposal container;

(D) the gross weight of the disposal container, including the waste;

(E) for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(F) a physical and chemical description of the waste;

(G) the total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(H) the approximate volume of waste within a container;

(I) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(J) the identities and activities of individual radionuclides contained in each container, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(K) the total radioactivity within each container; and

(L) for wastes consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified.

(8) Uncontainerized waste information. The shipper of the LLRW shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(A) the approximate volume and weight of the waste;

(B) a physical and chemical description of the waste;

(C) the total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;

(D) for waste consigned to a disposal facility, the classification of the waste in accordance with §289.202(ggg)(4)(A) of this title. Waste not meeting the structural stability requirements of §289.202(ggg)(4)(B)(ii) of this title shall be identified;

(E) the identities and activities of individual radionuclides contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(F) for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(9) Multi-generator disposal container information. This paragraph applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLRW resulting from a processor's activities may be attributable to one or more generators (including waste generators) as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

(A) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(B) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(i) the volume of waste within the disposal container;

(ii) a physical and chemical description of the waste, including the solidification agent, if any;

(iii) the total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(iv) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in §289.202(ggg)(4)(B)(ii) of this title; and

(v) radionuclide identities and activities contained in the waste, the masses of uranium-233, uranium-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

(10) Certification. An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the DOT and the department. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

(11) Control and tracking.

(A) Any licensee who transfers LLRW to a land disposal facility or a licensed waste collector shall comply with the requirements in clauses (i) - (ix) of this subparagraph. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of clauses (iv) - (ix) of this subparagraph. A licensee shall:

(i) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristic requirements in §289.202(ggg)(4)(B) of this title;

(ii) label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with §289.202(ggg)(4)(A) of this title;

(iii) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(iv) prepare the uniform manifest as required by this subsection;

(v) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the manifest precedes the LLRW shipment; and

(II) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(vi) include the uniform manifest with the shipment regardless of the option chosen in clause (v) of this subparagraph;

(vii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(viii) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title; and

(ix) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this subsection, conduct an investigation in accordance with subparagraph (D) of this paragraph.

(B) Any waste collector licensee who handles only prepackaged waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest to reflect consolidated shipments that meet the requirements of this subsection. The waste collector shall ensure that, for each container of waste in the shipment, the uniform manifest identifies the generator of that container of waste;

(iii) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclauses (I) and (II) of this clause are also acceptable;

(iv) include the uniform manifest with the shipment regardless of the option chosen in clause (iii) of this subparagraph;

(v) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(vi) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title;

(vii) for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with subparagraph (D) of this paragraph; and

(viii) notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(C) Any licensed waste processor who treats or repackages waste shall:

(i) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of the uniform manifest;

(ii) prepare a new uniform manifest that meets the requirements of this subsection. Preparation of the new uniform manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in clause (i) of this subparagraph;

(iii) prepare all wastes so that the waste is classified according to §289.202(ggg)(4)(A) of this title and meets the waste characteristics requirements in §289.202(ggg)(4)(B) of this title;

(iv) label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §289.202(ggg)(4)(A) and (C) of this title;

(v) conduct a quality assurance program to assure compliance with §289.202(ggg)(4)(A) and (B) of this title;

(vi) forward a copy or electronically transfer the uniform manifest to the intended consignee so that either:

(I) receipt of the uniform manifest precedes the LLRW shipment; or

(II) the uniform manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both subclause (I) of this clause and this subclause is also acceptable;

(vii) include the uniform manifest with the shipment regardless of the option chosen in clause (vi) of this subparagraph;

(viii) receive acknowledgement of the receipt of the shipment in the form of a signed copy of the uniform manifest;

(ix) retain a copy of or electronically store the uniform manifest and documentation of acknowledgement of receipt as the record of transfer of radioactive material as required by §289.251 of this title and §289.252 of this title;

(x) for any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in accordance with this clause, conduct an investigation in accordance with clause (v) of this subparagraph; and

(xi) notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance uniform manifest, unless notified by the shipper that the shipment has been cancelled.

(D) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in accordance with this section shall undergo the following:

(i) be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(ii) be traced and reported. The investigation shall include tracing the shipment and filing a report with the department. Each licensee who conducts a trace investigation shall file a written report with the department within two weeks of completion of the investigation.