25 TEXAS ADMINISTRTATIVE CODE

§289.252

Licensing of Radioactive Material

Texas Regulation for Control of Radiation

(Effective January 4, 2022)

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

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 and any 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 before 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 (cm^2); 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)

The receipt, possession, use, and transfer of this device, Model _____, Serial No._____ are subject to a general license or the equivalent and the regulations of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

(Name of Manufacturer or Distributor);

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

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

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or an equivalent license of the agency, the NRC, or any agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

(Name of Manufacturer or Distributor);

(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)

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals, and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____; or
Name of Manufacturer

(B) option 2:

Figure: 25 TAC §289.252(p)(3)(B)

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations of the agency, the NRC, or any agreement state.

_____; and
Name of Manufacturer

(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 (cm^2) 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) 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 10^5 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 10^5 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 10^{12} 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 10^{12} 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 10^4 but less than or equal to 10^5 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 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1);

(B) $225,000 for quantities of material greater than 10^3 but less than or equal to 10^4 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 10^3 is greater than 1 but R divided by 10^4 if less than or equal to 1);

(C) $113,000 for quantities of material greater than 10^{10} but less than or equal to 10^{12} 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 10^{10} is greater than 1, but R divided by 10^{12} 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 subsection (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.html and 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 during shipment.

(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)

RADIONUCLIDES	Limit	Unsealed Sources			Sealed Sources	
		10^3	10^4	10^5	10^{10}	10^{12}
Pr-141 Gd-152 Bi-209m U-232 Pu-240 Cm-245 Cf-252Ce-142 Dy-154 Po-208 U-233 Pu-241 Cm-246 Es-254Nd-144 Dy-156 Po-209 U-234 Pu-242 Cm-247 Nd-145 Tb-159 Po-210 U-235 Pu-244 Cm-248Sm-146 Ho-165 Ra-226 U-236 Am-241 Bk-247Sm-147 Hf-174 Ac-227 Np-235 Am-242m Bk-249Sm-148 W-180 Th-228 Np-237 Am-243 Cf-248 Gd-148 Pt-190 Th-229 Pu-236 Cm-242 Cf-249Gd-150 Pb-210 Th-230 Pu-238 Cm-243 Cf-250Gd-151 Bi-209 Pa-231 Pu-239 Cm-244 Cf-251 and any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition.	0.01 µCi	0.01 mCi	0.1 mCi	1.0 mCi	100 Ci	10 kCi
Be-10 Fe-60 Rh-102 Te-123 Sm-145 Lu-175 Ir-199m Al-26 Zn-70 Pd-107 Te-130 Nd-150 Lu-176 Pt-192 Si-32 Ge-68 Ag-108m I-129 Eu-150 Lu-177m Pt-198 Ar-39 Ge-76 Cd-113m La-137 Tb-157 Hf-172 Hg-194 K-40 Kr-81 Cd-116 La-138 Tb-158 Hf-182 Pb-202 Ar-42 Sr-90 Sn-121m Ce-139 Dy-159 Ta-179 Pb-205 Ca-48 Zr-96 Sn-123 Pm-143 Ho-166m Re-184m Bi-208 Ti-44 Mo-100 Sn-124 Pm-144 Lu-173 Re-187 Ra-228 V-49 Tc-98 Sn-126 Pm-145 Lu-174 Re-189 Np-236 V-50 Rh-101 Te-121m Pm-146 Lu-174m Os-194 Bk-248 and any radionuclide other than alpha-emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition.	0.1 µCi	0.1 mCi	1.0 mCi	10 mCi	1.0 kCi	100 kCi
Na-22 Ru-106 Cs-134 Eu-152 Bi-210 U (natural) Co-60 Ag-110m Ce-144 Eu-154 Th (natural)	1.0 µCi	1.0 mCi	10 mCi	100 mCi	10 kCi	1 MCi

Cl-36 Ca-45 Mn-54	Ni-63 Zn-65 Se-75	Rb-87 Zr-93 Nb-93m	Cd-109 In-115 Sb-125	Ba-133 Ba-135 Cs-137	Gd-153 Eu-155 Tm-170	Tm-171 W-181 Tl-204	10 µCi	10 mCi	100 mCi	1.0 Ci	100 kCi	10 MCi
C-14 Fe-55	Co-57 Ni-59	Kr-85 Tc-97	Tc-99 Pt-193,	Ir-194 Th-232	U-238		100 µCi	100 mCi	1.0 Ci	10 Ci	1.0MCi	100 MCi
H-3							1.0 mCi	1 Ci	10 Ci	100 Ci	10 MCi	1000 MCi

(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.

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Figure: 25 TAC §289.252(jj)(7)

Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)
Ac-228 (89)	0.001	4,000	In-114m (49)	0.01	1,000	V-48 (23)	0.01	7,000
Am-241 (95)	0.001	2	Ir-192 (77)	0.001	40,000	Xe-133 (54)	1.0	900,000
Am-242 (95)	0.001	2	Fe-55 (26)	0.01	40,000	Y-91 (39)	0.01	2,000
Am-243 (95)	0.001	2	Fe-59 (26)	0.01	7,000	Zn-65 (30)	0.01	5,000
Sb-124 (51)	0.01	4,000	Kr-85 (36)	1.0	6,000,000	Zr-93 (40)	0.01	400
Sb-126 (51)	0.01	6,000	Pb-210 (82)	0.01	8	Zr-95 (40)	0.01	5,000
Ba-133 (56)	0.01	10,000	Mn-56 (25)	0.01	60,000	Any other ß-γ emitter	0.01	10,000
Ba-140 (56)	0.01	30,000	Hg-203 (80)	0.01	10,000			
Bi-207 (83)	0.01	5,000	Mo-99 (42)	0.01	30,000	Mixed fission products	0.01	1,000
Bi-210 (83)	0.01	600	Np-237 (93)	0.001	2			
Cd-109 (48)	0.01	1,000	Ni-63 (28)	0.01	20,000	Mixed corrosion products	0.01	10,000
Cd-113 (48)	0.01	80	Nb-94 (41)	0.01	300			
Ca-45 (20)	0.01	20,000	P-32 (15)	0.5	100			
Cf-252 (98)	0.001	9(20mg)	P-33 (15)	0.5	1,000	Contaminated equipment, ß-γ	0.001	10,000
C-14 (6)**	0.01	50,000	Po-210 (84)	0.01	10			
Ce-141 (58)	0.01	10,000	K-42 (19)	0.01	9,000			
Ce-144 (58)	0.01	300	Pm-145 (61)	0.01	4,000	Irradiated material, any form other than solid non-combustible	0.01	1,000
Cs-134 (55)	0.01	2,000	Pm-147 (61)	0.01	4,000			
Cs-137 (55)	0.01	3,000	Ra-226 (88)	0.001	100			
Cl-36 (17)	0.5	100	Ru-106 (44)	0.01	200			
Cr-51 (24)	0.01	300,000	Sm-151 (62)	0.01	4,000			
Co-60 (27)	0.001	5,000	Sc-46 (21)	0.01	3,000			
Cu-64 (29)	0.01	200,000	Se-75 (34)	0.01	10,000	Irradiated material, solid non-combustible	0.001	10,000
Cm-242 (96)	0.001	60	Ag-110m (47)	0.01	1,000			
Cm-243 (96)	0.001	3	Na-22 (11)	0.01	9,000			
Cm-244 (96)	0.001	4	Na-24 (11)	0.01	10,000			
Cm-245 (96)	0.001	2	Sr-89 (38)	0.01	3,000	Mixed radioactive waste, ß-γ	0.01	1,000
Eu-152 (63)	0.01	500	Sr-90 (38)	0.01	90			
Eu-154 (63)	0.01	400	S-35 (16)	0.5	900			
Eu-155 (63)	0.01	3,000	Tc-99 (43)	0.01	10,000	Packaged waste, ß-γ ***	0.001	10,000
Ge-68 (32)	0.01	2,000	Tc-99m (43)	0.01	400,000			
Gd-153 (64)	0.01	5,000	Te-127m(52)	0.01	5,000			
Au-198 (79)	0.01	30,000	Te-129m(52)	0.01	5,000			

Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)	Radioactive Material*	Release Fraction	Quantity (curies)	
Hf-172 (72)	0.01	400		Tb-160 (65)	0.01	4,000	Any other α emitter	0.001	2
Hf-181 (72)	0.01	7,000		Tm-170 (69)	0.01	4,000			
Ho-166 (67)	0.01	100		Sn-113 (50)	0.01	10,000	Contaminated equipment α	0.0001	20
H-3 (1)	0.5	20,000		Sn-123 (50)	0.01	3,000			
I-125 (53)	0.5	10		Sn-126 (50)	0.01	1,000	Packaged waste α ***	0.0001	20
I-131 (53)	0.5	10		Ti-44 (22)	0.01	100			

* For combinations of radionuclides, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radionuclide authorized to the quantity listed for that radionuclide in this paragraph exceeds one. ( ) indicates atomic number.

** Non CO forms only.

*** Waste packaged in Type B containers does not require an emergency plan.

(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)

Category 1 and Category 2 Radioactive Material Thresholds

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive Material	**Category 1(TBq)**	**Category 1(Ci)**	**Category 2(TBq)**	**Category 2(Ci)**
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note**:** Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a

location meets or exceeds the threshold and is thus subject to the requirements of §289.252(ii) of this title.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds in Figure: 25 TAC §289.252(jj)(9), as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of §289.252(ii) of this title apply.

II. First determine the total activity for each radionuclide from Figure: 25 TAC §289.252(jj)(9). This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides in the numerator of the equation and, in the denominator of the equation, the corresponding activity threshold from Figure: 25 TAC §289.252(jj)(9) which is applicable.

Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_N = total activity for radionuclide n
AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_N = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$

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(10) Broad scope license limits (for use in subsection (h) of this section).

Figure: 25 TAC §289.252(jj)(10)

Broad Scope License Limits

Radioactive Material	Type B curies	Type C curies
Antimony-122	1	.01
Antimony-124	1	.01
Antimony-125	1	.01
Arsenic-73	10	.1
Arsenic-74	1	.01
Arsenic-76	1	.01
Arsenic-77	10	.1
Barium-131	10	.1
Barium-140	1	.01
Beryllium-7	10	.1
Bismuth-210	.1	.001
Bromine-82	10	.1
Cadmium-109	1	.01
Cadmium-115m	1	.01
Cadmium-115	10	.1
Calcium-45	1	.01
Calcium-47	10	.1
Carbon-14	100	1
Cerium-141	10	.1
Cerium-143	10	.1
Cerium-144	.1	.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	.1	.001
Cesium-135	1	.01
Cesium-136	10	.1
Cesium-137	.1	.001
Chlorine-36	1	.01
Chlorine-38	100	1
Chromium-51	100	1
Cobalt-57	10	.1
Cobalt-58m	100	1
Cobalt-58	1	.01
Cobalt-60	.1	.001
Copper-64	10	.1
Dysprosium-165	100	1
Dysprosium-166	10	.1
Erbium-169	10	.1
Erbium-171	10	.1
Europium-152 9.2 h	10	.1

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Figure: 25 TAC §289.252(jj)(10)

Radioactive Material	Type B curies	Type C curies
Europium-152 13 y	.1	.001
Europium-154	.1	.001
Europium-155	1	.01
Fluorine-18	100	1
Gadolinium-153	1	.01
Gadolinium-159	10	.1
Gallium-72	10	.1
Germanium-71	100	1
Gold-198	10	.1
Gold-199	10	.1
Hafnium-181	1	.01
Holmium-166	10	.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	.01
Indium-115m	100	1
Indium-115	1	.01
Iodine-125	.1	.001
Iodine-126	.1	.001
Iodine-129	.1	.01
Iodine-131	.1	.001
Iodine-132	10	.1
Iodine-133	1	.01
Iodine-134	10	.1
Iodine-135	1	.01
Iridium-192	1	.01
Iridium-194	10	.1
Iron-55	10	.1
Irion-59	1	.01
Krypton-85	100	1
Krypton-87	10	.1
Lanthanum-140	1	.01
Lutelium-177	10	.1
Manganese-52	1	.01
Manganese-54	1	.01
Manganese-56	10	.1
Mercury-197m	10	.1
Mercury-197	10	.1
Mercury-203	1	.01
Molybdenum-99	10	.1
Neodymium-147	10	.1
Neodymium-149	10	.1
Nickel-59	10	.1
Nickel-63	1	.01

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Figure: 25 TAC §289.252(jj)(10)

Radioactive Material	Type B curies	Type C curies
Nickel-65	10	.1
Niobium-93m	1	.01
Niobium-95	1	.01
Niobium-97	100	1
Osmium-185	1	.01
Osmium-191m	100	1
Osmium-191	10	.1
Osmium-193	10	.1
Palladium-103	10	.1
Palladium-109	10	.1
Phosphorus-32	1	.01
Platinum-191	10	.1
Platinum-193m	100	1
Platinum-193	10	.1
Platinum-197m	100	1
Platinum-197	10	.1
Polonium-210	.01	.0001
Potassium-42	1	.01
Praseodymium-142	10	.1
Praseodymium-143	10	.1
Promethium-147	1	.01
Promethium-149	10	.1
Radium-226	0.01	0.0001
Rhenium-186	10	.1
Rhenium-188	10	.1
Rhodium-103m	1,000	10.
Rhodium-105	10	.1
Rubidium-86	1	.01
Rubidium-87	1	.01
Ruthenium-97	100	1
Ruthenium-103	1	.01
Ruthenium-105	10	.1
Ruthenium-106	.1	.001
Samarium-151	1	.01
Samarium-153	10	.1
Scandium-46	1	.01
Scandium-47	10	.1
Scandium-48	1	.01
Selenium-75	1	.01
Silicon-31	10	.1
Silver-105	1	.01
Silver-110m	.1	.001
Silver-111	10	.1
Sodium-22	0.1	.001

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Figure: 25 TAC §289.252(jj)(10)

Radioactive Material	Type B curies	Type C curies
Sodium-24	1	.01
Strontium-85m	1,000	10
Strontium-85	1	.01
Strontium-89	1	.01
Strontium-90	.01	.0001
Strontium-91	10	.1
Strontium-92	10	.1
Sulphur-35	10	.1
Tantalum-182	1	.01
Technetium-96	10	.1
Technetium-97m	10	.1
Technetium-97	10	.1
Technetium-99m	100	1
Technetium-99	1	.01
Tellurium-125m	1	.01
Tellurium-127m	1	.01
Tellurium-127	10	.1
Tellurium-129m	1	.01
Tellurim-129	100	1
Tellurium-131m	10	.1
Tellurium-132	1	.01
Terbium-160	1	.01
Thallium-200	10	.1
Thallium-201	10	.1
Thallium-202	10	.1
Thallium-204	1	.01
Thulium-170	1	.01
Thulium-171	1	.01
Tin-113	1	.01
Tin-125	1	.01
Tungsten-181	1	.01
Tungsten-185	1	.01
Tungsten-187	10	.1
Vandadium-48	1	.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	.1
Yttrium-90	1	.01
Yttrium-91	1	.01
Yttrium-92	10	.1
Yttrium-93	1	.01
Zinc-65	1	.01
Zinc-69m	10	.1

Figure: 25 TAC §289.252(jj)(10)

Radioactive Material	Type B curies	Type C curies
Zinc-69	100	1
Zirconium-93	1	.01
Zirconium-95	1	.01
Zirconium-97	1	.01
Any radioactive material other than alpha emitting radioactive material not listedabove	.1	.001

(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)

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Record/Document
(l)(7)(D)	Documentation of all receipts and transfers for the manufacture and commercial distribution of devices	3 years after the date of the event (i.e. receipt or transfer)
(r)(2)(C)	Records of tests and checks of measurements of the radioactivity of radioactive drugs	A minimum of 3 years after when the record was made
(r)(3)(G)	A complete description of any deviation from the manufacturer's instructions when eluting generators or processing radioactive materials with a reagent kit	3 years after the record was made
(s)(4)(G)	Records including the name, address, and point of contact for each general licensee to whom depleted uranium in products or devices is distributed	2 years after the record was made
(x)(10)	Test results and records for generator eluates of molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination	3 years after the record was made
(cc)(6)(B)(v)	All information supporting the report of a transfer of small quantities of source material	1 year after the transfer event is included in a report to the agency, the NRC, or any agreement state
(gg)(7)	Records of information important to the safe and effective decommissioning of the facility	Until the license is terminated by the agency
(ii)(3)(G)(i)	Confirmation of receipt of a notification to the individual of the right to complete, correct and explain any reasons for denial of personnel access authorization	1 year after the date of the notification
(ii)(3)(H)(i)	Documentation regarding the trustworthiness and reliability of individual employees	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(3)(H)(ii)	Copy of the current access authorization program procedures	3 years after the procedure is no longer needed
(ii)(3)(H)(ii)	Superseded material for any portion(s) of the access authorization program procedures that is superseded	3 years after the procedure or any portion(s) of the procedure is superseded

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Record/Document
(ii)(3)(H)(iii)	List of persons approved for unescorted access authorization	3 years after the list is superseded or replaced
(ii)(4)(A)(ii)	Certification in writing that each individual employee's identification was properly reviewed, and any documents used for the review	3 years after the date an individual granted unescorted access to category 1 or category 2 quantities of radioactive material no longer requires such access, or, for an individual denied access, 3 years from the date the record was made
(ii)(6)(A)(xii)	Written confirmation of an active security clearance from the agency or employer that granted the clearance or reviewed the criminal history records check of the individual	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(6)(A)(xiii)	Written verification from a service provider licensee for an individual employed by that service provider that it has conducted a background investigation for the individual and approved that individual for unescorted access to category 1 or category 2 quantities of radioactive material	3 years after the date the individual employee no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(6)(B)	Written confirmation from an agency or employer that reviewed the criminal history records check 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	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(7)(E)	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	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material

§289.252 Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Record/Document
(ii)(8)(C)	Access authorization program review records	3 years after the record was made
(ii)(10)(A)(iv)	Copy of the current security plan	3 years after the record is no longer needed
(ii)(10)(A)(iv)	Copy of superseded material from any portion of the security plan that is superseded	3 years after the record is superseded
(ii)(10)(B)(iii)	Copy of the current implementing procedures	3 years after the procedure is no longer needed
(ii)(10)(B)(iii)	Any superseded portion(s) of the implementing procedures	3 years after the record is superseded
(ii)(10)(C)(iv)	Copies of initial and refresher training	3 years after the date of the training
(ii)(10)(D)(viii)(I)	Copy of the information protection procedures	3 years after the document is no longer needed
(ii)(10)(D)(viii)(II)	List of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access	3 years after the document is no longer needed
(ii)(11)(C)	Documentation of the licensee's efforts to coordinate with the LLEA	3 years after the record was made
(ii)(14)(B)	Records on maintenance and testing activities	3 years after the record was made
(ii)(16)(C)	Security program review documentation	3 years after the record was made
(ii)(18)(D)	Verification documentation for any transfer of category 1 or category 2 quantity of radioactive material	3 years after the record was made
(ii)(20)(E)	Documentation, and any revisions thereof, for the preplanning and coordination of shipments of category 1 or category 2 quantities of radioactive material	3 years after the record was made
(ii)(21)(E)	Copy of the advance notification and any revision and cancellation notices for the shipment of category 1 quantities of radioactive material through or across boundaries of a State	3 years after the record was made
(ll)(2)	Documentation of any installation, repair, or maintenance of devices containing sealed sources of radioactive material	5 years after date of service