25 TEXAS ADMINISTRATIVE CODE (TAC)

§289.252

Licensing of Radioactive Material

Texas Regulations for Control of Radiation

(revisions effective March 22, 2015, are shown as shaded text)

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§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 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/or any of the following sections:

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

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

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

(iv) §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 receives, possesses, uses, transfers, owns, or acquires radioactive materials prior to receiving a license is subject to the requirements of this chapter.

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

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

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

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

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

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

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

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

(2) Licensees engaged in well logging service operations and tracer studies are subject to the requirements of §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies).

(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 agency or the issuance of licensing documents to the particular persons, although the filing of an application for acknowledgement with the agency may be required for a particular general license. The general licensee is subject to any other applicable portions of this chapter and any limitations of the general license.

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

(d) Filing application for specific licenses. The agency may, at any time after the filing of the original application, require further statements in order to enable the agency 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 agency.

(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 agency may require the issuance of separate specific licenses for those activities.

(4) 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.

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

(6) Each applicant shall demonstrate to the agency that the applicant is financially qualified to conduct the activity requested for licensure, including any required decontamination, decommissioning, reclamation, and disposal before the agency issues a license. Each licensee shall demonstrate to the agency 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.

(7) 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, 22 Texas Administrative Code, Chapter 131.

(8) 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 Division of Licensing, Registration and Standards 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 Government Code, Chapter 2001.

(9) 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 NRC, an agreement state, or a licensing 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.

(10) 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, an agreement state, or a licensing 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.

(11) 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.

(12) 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.

(13) 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 (8) 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% 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.

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

(A) any material 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 agency to refuse to grant a license on an application; or

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

(15) 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 agency. 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) - (7) of this subsection.

(e) General requirements for the issuance of specific licenses. A license application will be approved if the agency 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 and the environment;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to occupational and public health and safety 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 and/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)(14) or (x)(9) of this section; and

(11) the applicant is listed on the Secretary of State's website as authorized 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 with the Secretary of State and/or the office of the county clerk as required under the Business and Commerce Code, Chapter 71.

(f) Radiation safety officer.

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

(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) The specific duties of the RSO include, but are not limited to, 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/or 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 agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;

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

(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/or 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 six months and make and maintain records of the inventory of the radioactive sealed sources authorized for use on the license every six months, to include, but not be limited to 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 agency; and

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

(4) Requirements for RSOs for specific licenses for broad scope authorization for research and development. In addition to the requirements in paragraphs (1) and (3) 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 four 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 three years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

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

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

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

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

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

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

(D) equivalent qualifications as approved by the agency.

(5) The qualifications in paragraph (4)(A) - (D) do not apply to individuals who have been adequately trained and designated as RSOs on licenses issued prior to October 1, 2000.

(g) The duties and responsibilities of the Radiation Safety Committee (RSC) include but are not limited to 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 prior to implementation; and

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

(h) Specific licenses for broad scope authorization for multiple quantities or types of radioactive material for use in research and development.

(1) In addition to the requirements in subsection (e) of this section, a specific license for multiple quantities or types of radioactive material for use in research and development, not to include the internal or external administration of radiation or radioactive material to humans, will be issued if the agency approves the following documentation submitted by the applicant:

(A) that staff has substantial experience in the use of a variety of radioisotopes for a variety of research and development uses;

(B) of a full-time RSO meeting the requirements of subsection (f)(4) of this section;

(C) establishment of an RSC, including names and qualifications, with duties and responsibilities in accordance with subsection (g) of this section. The RSC shall be composed of an RSO, a representative of executive management, and one or more persons trained or experienced in the safe use of radioactive materials.

(2) Unless specifically authorized, persons licensed according to paragraph (1) of this subsection shall not conduct tracer studies involving direct release of radioactive material to the environment.

(3) Unless specifically authorized, in accordance with a separate license, persons licensed according to paragraph (1) of this subsection shall not:

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

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

(C) 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

(D) commercially distribute radioactive material.

(i) Specific licenses for introduction of radioactive material into products in exempt concentrations.

(1) In addition to the requirements in subsection (e) of this section, a specific license authorizing the introduction of radioactive material into a product or material in the possession of the licensee or another to be transferred to persons exempt from this chapter in accordance with §289.251(e)(1)(A) of this title will be issued if the agency approves the following information submitted by the applicant:

(A) a description of the product or material into which the radioactive material will be introduced;

(B) intended use of the radioactive material and the product or material into which it is introduced;

(C) method of introduction;

(D) initial concentration of the radioactive material in the product or material;

(E) control methods to assure that no more than the specified concentration is introduced into the product or material;

(F) estimated time interval between introduction and transfer of the product or material;

(G) estimated concentration of the radioactive material in the product or material at the time of transfer; and

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

(2) the applicant provides reasonable assurance that:

(A) the concentrations of radioactive material at the time of transfer will not exceed the concentrations in §289.251(m)(1) of this title;

(B) reconcentration of the radioactive material in concentrations exceeding those in §289.251(m)(1) of this title will not occur;

(C) the use of lower concentrations is not feasible; and

(D) the product or material is not to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human.

(3) Each person licensed in accordance with this subsection shall file an annual report with the agency and shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period. The report shall cover the year ending June 30, shall be filed within 30 days thereafter, and shall include the following:

(A) name and address of the person who owned or possessed the product or material when the radioactive material was introduced;

(B) the type and quantity of radionuclide introduced into each such product or material; and

(C) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(4) If no transfers of radioactive material have been made in accordance with this subsection during the reporting period, the report shall so indicate.

(5) 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, an agreement state, or a licensing state will be issued if the agency 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 10% 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 agency 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:

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

> 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:

> 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 a licensing 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 six 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 agency will consider information that includes, but is not limited to 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, an agreement state, or a licensing 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 10% 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, agreement state's, or licensing 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, the agreement state, or the licensing 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, agreement state, or licensing 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 agency, an agreement state, or licensing state, or the NRC 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 agency.

(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 prior to 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 agency 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 agency 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 prior to 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 appropriate agreement state or licensing 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) the type, model and serial number of the device, and serial number of sealed source commercially distributed;

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

(VIII) date of receipt.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to 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 or licensing 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) keep records for three years following the date of the recorded event, showing 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, an agreement state, or a licensing state.

(i) The records shall show the following:

(I) 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 under this subsection shall provide, upon request to the NRC and to any appropriate agreement state or licensing state, records of final disposition required under 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 agency 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 agency 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, an agreement state, or a licensing 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 under §289.251(f)(4)(D) of this title or equivalent regulations of the NRC, an agreement state, or a licensing 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 agency 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 agency for commercial distribution to persons licensed for use of sealed sources in the healing arts or by equivalent licenses of the NRC, an agreement state, or a licensing 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 six 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, but is not limited to 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 agency 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) each;

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

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

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

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

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

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

(H) mock iodine-125 in units not exceeding 0.05 µCi (1.85 kilobecquerels) of iodine-129 and 0.005 µCi (0.185 kilobecquerel) 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 megabecquerel) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 µCi (1.85 megabecquerels) of hydrogen-3 (tritium); 20 µCi (0.74 megabecquerel) of iron-59; or mock iodine-125 in units not exceeding 0.05 µCi (1.85 kilobecquerels) of iodine-129 and 0.005 µCi (0.185 kilobecquerel) 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:

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:

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 a licensing 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 agency 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.

(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 agency 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, §207.20(a);

(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;

(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; and

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

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

(III) 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 prior to 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) maintain records of the tests and checks in this paragraph for a minimum of three years for inspection by the agency.

(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 agency, 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) 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 prior to the effective date of this rule as noticed by the NRC or the agency.

(E) Provide the following to the agency:

(i) a copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC, agency, or an agreement state as specified in §289.256(k)(1) of this title with the written attestation signed by a preceptor as required by §289.256(k)(2)(C) of this title; or

(ii) the agency, 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 prior to the effective date of this rule as noticed by the NRC or the agency; 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 agency for a period of three years.

(4) 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 agency 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 10% 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 agency 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 agency 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 agency 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/or position who may constitute a point of contact between the agency 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) keep records showing 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 of an agreement state. The records shall be maintained for a period of two years for inspection by the agency and shall show 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 agency approves the following information submitted by the applicant:

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

(2) intended use of each radionuclide and the sealed sources and/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, but not be limited to:

(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 agency approves the following information submitted by the applicant:

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

(2) the intended use of each radionuclide and the sealed sources and/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 shall submit a request to the agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review shall be sent to the Radiation Safety Licensing Branch in accordance with §289.201(k) of this title and shall be submitted in duplicate accompanied by the appropriate fee 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 agency 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 agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The agency 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 agency issues a sealed source and device (SS & D) registration to the person making the request. The SS & D 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 registration.

(7) The person submitting the request for evaluation and SS & D 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 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 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 this section or equivalent regulations of the NRC, an agreement state, or a licensing 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 registration is issued, the agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the agency will complete its evaluation in accordance with criteria specified in this section. The agency may request such additional information as it considers necessary to conduct its review and the SS & D registration holder shall provide the information as requested.

(10) Inactivation of SS & D registrations.

(A) An SS & D registration holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular SS & D registration issued by the agency shall request inactivation of the SS & D registration. Such a request shall be made to the Radiation Safety Licensing Branch by an appropriate method in accordance with §289.201(k) of this title and shall normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the SS & D registration has ceased. However, if the SS & D registration holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the SS & D registration holder shall request inactivation of the SS & D 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 registration(s) associated with that distribution license before the agency will terminate the license. Such a request for inactivation of the SS & D registration(s) 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 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 registration, including in the case of an inactive SS & D registration.

(w) Issuance of specific licenses.

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

(2) The agency 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 agency 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 agency may request, and the licensee shall provide, additional information after the license has been issued to enable the agency 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 agency.

(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 agency 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 agency, 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 agency 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 agency.

(5) The licensee shall notify the agency, 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 agency's Radiation Safety Licensing Branch, 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 (5) 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 agency along with the written notification.

(9) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a license, the agency may consider the technical competence and compliance history of an applicant or holder of a license. After an opportunity for a hearing, the agency shall 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 agency 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. The licensee shall record the results of each test and retain each record for 3 years after the record is made for inspection by the agency.

(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 agency 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 agency in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building and/or 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;

(C) no principal activities under 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 agency approval, to cover the detailed cost estimate for decommissioning established in accordance with paragraph (10)(E) of this subsection.

(6) The agency may grant a request to delay or postpone initiation of the decommissioning process if the agency 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 agency 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 agency 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 agency may approve an alternate schedule for submittal of a decommissioning plan required in accordance with paragraph (4) of this subsection if the agency 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 prior to 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 agency 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 agency 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 agency 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 agency 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 and tested.

(16) The agency 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 agency will provide such notification when the agency 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 agency all records required by §289.202(nn)(2) 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) - (3) and (5) - (7) of this section. In any application for renewal, the applicant may incorporate drawings by clear and specific reference (for example, title, date and unique number of drawing), if no modifications have been made since previously submitted.

(2) In any case in which a licensee, not less than 30 days prior to 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 agency. 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 agency may reinstate the license and extend the expiration until the request has been finally determined by the agency. The requirements in this subsection are subject to the provisions of Government Code, §2001.054.

(3) An application for technical renewal of a license will be approved if the agency 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) - (3) 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)(3) and (15) of this section.

(bb) Agency action on requests to renew or amend. In considering a request by a licensee to renew or amend a license, the agency 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 agency (A licensee may transfer material to the agency only after receiving prior approval from the agency.);

(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 agency, the NRC, any agreement state, or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency of the federal government, the agency, any agreement state, or any licensing state; or

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

(3) Before transferring radioactive material to a specific licensee of the agency, the NRC, an agreement state, or a licensing state, or to a general licensee who is required to register with the agency, the NRC, an agreement state, or a licensing state prior to 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 agency, the NRC, or the licensing agency of an agreement state or a licensing 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.

(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 agency.

(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 agency 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 agency; 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 agency ends at the end of the day on the date of the agency's final determination to revoke the license, or on the revocation date stated in the determination, or as otherwise provided by the agency order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no license shall be suspended or revoked unless, prior to 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 NRC, any agreement state, or any licensing 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 agency in writing at least three working days prior to 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 agency, obtain permission to proceed sooner. The agency 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; and

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

(C) the out-of-state licensee complies with all applicable rules of the agency 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 agency;

(D) the out-of-state licensee supplies such other information as the agency 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 agency, the NRC, another agreement state, or another licensing 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 agency review upon request:

(i) a copy of the agency 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 agency 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 NRC, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install, or service the device described in §289.251(f)(4)(H) of this title, 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:

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(A) the person files a report with the agency 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, an agreement state, or a licensing 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 agency 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 agency 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 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 agency 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 agency 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 but less than or equal to 100 mCi 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 (5) 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 (5) 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 agency, but shall be submitted to the agency prior to 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 agency. The applicant or licensee shall obtain written approval of the financial instrument or any amendment to it from the agency.

(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 prior to the renewal date, the issuer notifies the agency, 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 prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency 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 agency 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 (4) 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 keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency 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 and/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; and

(iii) all areas outside of restricted areas where current and previous wastes have been buried as documented in accordance with §289.202(tt) 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 agency; 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 agency 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 agency.

(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 agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

(ii) Increased controls (ICs). Licensees possessing sources containing radioactive material, at any given time, in quantities greater than or equal to the quantities of concern listed in subsection (jj)(9) of this section shall:

(1) control access at all times to radioactive material and devices containing such radioactive material (devices) in quantities in accordance with subsection (jj)(9) of this section; and

(2) limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

(A) The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern (RAM QC) and devices.

(B) The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.

(C) For individuals employed by the licensee for three years or less, and for non-licensee personnel, such as physicians, physicists, house-keeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.

(D) Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the M&D licensee providing the service.

(E) The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of RAM QC. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

(3) Each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to RAM QC and devices in use or in storage. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the values listed in subsection (jj)(9) of this section.

(A) The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a Local Law Enforcement Agency (LLEA).

(B) The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with a realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Prearranged LLEA coordination is not required for temporary job sites.

(C) The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

(D) After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the NRC Operations Center at (301) 816-5100.

(E) The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.

(4) In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed but are less than 100 times those listed in subsection (jj)(9) of this section, per consignment, the licensee shall:

(A) Use carriers which:

(i) use package tracking systems;

(ii) implement methods to assure trustworthiness and reliability of drivers;

(iii) maintain constant control and/or surveillance during transit; and

(iv) have the capability for immediate communication to summon appropriate response or assistance.

(B) Verify and document that the carrier employs the measures in subparagraph (A) of this paragraph;

(C) Contact the recipient to coordinate the expected arrival time of the shipment;

(D) Confirm receipt of the shipment; and

(E) Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or is missing, the licensee shall immediately notify the NRC Operations Center at (301) 816-5100. If, after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be deemed missing and the licensee shall immediately notify the NRC Operations Center at (301) 816-5100.

(5) For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in subsection (jj)(9) of this section per consignment, the licensee shall:

(A) Notify the NRC Director, Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission, Washington, DC 20555, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of RAM QC. The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by the NRC.

(B) Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements in subparagraph (A) of this paragraph shall not apply to future shipments of licensed radioactive material that exceeds 100 times the quantities listed in subsection (jj)(9) of this section. The licensee shall implement the ASMs for the transportation of RAM QC.

(6) If a licensee employs an M&D licensee to take possession at the licensee's location of the licensed radioactive material and ship it under its M&D license, the requirements of paragraph (5)(A) and (B) of this subsection shall not apply.

(7) If the licensee is to receive radioactive material greater than or equal to the quantities in subsection (jj)(9) of this section, per consignment, the licensee shall coordinate with the originator to:

(A) Establish an expected time of delivery; and

(B) Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originator and assist in any investigation.

(8) Each licensee who possesses mobile or portable devices containing radioactive material in quantities greater than or equal to the values listed in subsection (jj)(9) of this section, shall:

(A) For portable devices, 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.

(B) For mobile devices:

(i) that are only moved outside of the facility (e.g., on a trailer), 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.

(ii) that are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.

(C) For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

(9) The licensee shall retain documentation required by these ICs for inspection by the agency for three years after they are no longer effective.

(A) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.

(B) Each time the licensee revises the list of approved persons required by paragraph (2)(E) of this subsection, or the documented program required by paragraph (3) of this subsection, the licensee shall retain the previous documentation for three years after the revision.

(C) The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.

(D) The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.

(E) After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these ICs for three years.

(10) Detailed information generated by the licensee that describes the physical protection of RAM QC, is sensitive information and shall be protected from unauthorized disclosure.

(A) The licensee shall control access to its physical protection information to those persons who have an established need to know the information, and are considered to be trustworthy and reliable.

(B) The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, its physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

(i) general performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure;

(ii) protection of sensitive information during use, storage, and transit;

(iii) preparation, identification or marking, and transmission;

(iv) access controls;

(v) destruction of documents;

(vi) use of automatic data processing systems; and

(vii) removal from the licensee's sensitive information category.

(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;

(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).

(2) Isotope quantities (for use in subsection (gg) of this section).

RADIONUCLIDES	Limit	Unsealed Sources			Sealed Sources
		10^3	10^4	10^5	10^{10}
Pr-141 Gd-152 Bi-209m U-232 Pu-240 Cm-245 Cf-252 Ce-142 Dy-154 Po-208 U-233 Pu-241 Cm-246 Es-254 Nd-144 Dy-156 Po-209 U-234 Pu-242 Cm-247 Nd-145 Tb-159 Po-210 U-235 Pu-244 Cm-248 Sm-146 Ho-165 Ra-226 U-236 Am-241 Bk-247 Sm-147 Hf-174 Ac-227 Np-235 Am-242m Bk-249 Sm-148 W-180 Th-228 Np-237 Am-243 Cf-248 Gd-148 Pt-190 Th-229 Pu-236 Cm-242 Cf-249 Gd-150 Pb-210 Th-230 Pu-238 Cm-243 Cf-250 Gd-151 Bi-209 Pa-231 Pu-239 Cm-244 Cf-251 and any alpha-emitting radionuclide not listed above or mixtures of unknown alpha emitters of unknown composition.	0.01 µCi	0.01 mCi	0.1 mCi	1.0 mCi	100 Ci
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 other 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
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
Cl-36 Ni-63 Rb-87 Cd-109 Ba-133 Gd-153 Tm-171 Ca-45 Zn-65 Zr-93 In-115 Ba-135 Eu-155 W-181 Mn-54 Se-75 Nb-93m Sb-125 Cs-137 Tm-170 Tl-204	10 µCi	10 mCi	100 mCi	1.0 Ci	100 kCi
C-14, Co-57 Kr-85 Tc-99 Ir-194 U-238 Fe-55 Ni-59 Tc-97 Pt-193, Th-232	100 µCi	100 mCi	1.0 Ci	10 Ci	1.0MCi
H-3	1.0 mCi	1 Ci	10 Ci	100 Ci	10 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% 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% 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 agency 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 agency of intent to establish alternate financial assurance as specified in the agency'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 agency. 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 agency, as evidenced by the return receipts;

(ii) if the licensee fails to provide alternate financial assurance as specified in the agency's rules within 90 days after receipt by the licensee and the agency 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 agency has terminated the license; and

(iv) if a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the agency. 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% 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 agency 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 agency of its intent to establish alternate financial assurance as specified in the agency'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 agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt;

(ii) the licensee shall provide alternate financial assurance as specified in the agency's rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee;

(iii) the guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee;

(iv) the licensee will promptly forward to the agency 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 agency 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 agency 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 agency, 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% 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 agency 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 agency of intent to establish alternative financial assurance as specified in the agency'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 agency. 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 agency rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the agency 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 agency, 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.

(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;

(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 license.

(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 agency 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;

(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 agency of its intent to establish alternative financial assurance as specified in the agency'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, and/or return receipt requested, to the agency. 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 agency's regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

(iii) The guarantee and financial test provisions shall remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

(iv) The applicant or licensee shall provide to the agency 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 agency, 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 agency 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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Radioactive Material*	Release Fraction	Quantity (curies)
Ac-228 (89)	0.001	4,000
Am-241 (95)	0.001	2
Am-242 (95)	0.001	2
Am-243 (95)	0.001	2
Sb-124 (51)	0.01	4,000
Sb-126 (51)	0.01	6,000
Ba-133 (56)	0.01	10,000
Ba-140 (56)	0.01	30,000
Bi-207 (83)	0.01	5,000
Bi-210 (83)	0.01	600
Cd-109 (48)	0.01	1,000
Cd-113 (48)	0.01	80
Ca-45 (20)	0.01	20,000
Cf-252 (98)	0.001	9(20mg)
C-14 (6)**	0.01	50,000
Ce-141 (58)	0.01	10,000
Ce-144 (58)	0.01	300
Cs-134 (55)	0.01	2,000
Cs-137 (55)	0.01	2,000
Cl-36 (17)	0.5	100
Cr-51 (24)	0.01	300,000
Co-60 (27)	0.001	5,000
Cu-64 (29)	0.01	200,000
Cm-242 (96)	0.001	60
Cm-243 (96)	0.001	3
Cm-244 (96)	0.001	4
Cm-245 (96)	0.001	2
Eu-152 (63)	0.01	500
Eu-154 (63)	0.01	400
Eu-155 (63)	0.01	3,000
Ge-68 (32)	0.01	2,000
Gd-153 (64)	0.01	5,000
Au-198 (79)	0.01	30,000
Hf-172 (72)	0.01	400
Hf-181 (72)	0.01	7,000
Ho-166 (67)	0.01	100
H-3 (1)	0.5	20,000
I-125 (53)	0.5	10
I-131 (53)	0.5	10
In-114m (49)	0.01	1,000
Ir-192 (77)	0.001	40,000
Fe-55 (26)	0.01	40,000
Fe-59 (26)	0.01	7,000
Kr-85 (36)	1.0	6,000,000
Pb-210 (82)	0.01	8
Mn-56 (25)	0.01	60,000
Hg-203 (80)	0.01	10,000
Mo-99 (42)	0.01	30,000
Np-237 (93)	0.001	2
Ni-63 (28)	0.01	20,000
Nb-94 (41)	0.01	300
P-32 (15)	0.5	100
P-33 (15)	0.5	1,000
Po-210 (84)	0.01	10
K-42 (19)	0.01	9,000
Pm-145 (61)	0.01	4,000
Pm-147 (61)	0.01	4,000
Ra-226 (88)	0.001	100
Ru-106 (44)	0.01	200
Sm-151 (62)	0.01	4,000
Sc-46 (21)	0.01	3,000
Se-75 (34)	0.01	10,000
Ag110m (47)	0.01	1,000
Na-22 (11)	0.01	9,000
Na-24 (11)	0.01	10,000
Sr-89 (38)	0.01	3,000
Sr-90 (38)	0.01	90
Sr-35 (16)	0.5	900
Tc-99 (43)	0.01	10,000
Tc-99m (43)	0.01	400,000
Te-127m(52)	0.01	5,000
Te-129m(52)	0.01	5,000
Tb-160 (65)	0.01	4,000
Tm-170 (69)	0.01	4,000
Sn-113 (50)	0.01	10,000
Sn-123 (50)	0.01	3,000
Sn-126 (50)	0.01	1,000
Ti-144 (22)	0.01	100
V-48 (23)	0.01	7,000
Xe-133 (54)	1.0	900,000
Y-91 (39)	0.01	2,000
Zn-65 (30)	0.01	5,000
Zr-93 (40)	0.01	400
Zr-95 (40)	0.01	5,000
Any other β-γ emitter	0.01	10,000
Mixed fission products	0.01	1,000
Mixed corrosion products	0.01	10,000
Contaminated equipment, β-γ	0.001	10,000
Irradiated material, any form other than solid non-combustible	0.01	1,000
Irradiated material, solid non-combustible	0.001	10,000
Mixed radioactive waste, β-γ	0.01	1,000
Packaged waste, β-γ ***	0.001	10,000
Any other α emitter	0.001	2
Contaminated equipment α	0.0001	20
Packaged waste***	0.0001	20

* 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 agency 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 ratios 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) SEC 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).

(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 agency 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 agency 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) Radionuclide quantities of concern. The following methods shall be used to determine which sources of radioactive material require ICs:

(A) include any single source equal to or greater than the quantity of concern;

(B) include multiple collocated sources of the same radionuclide when the combined quantity equals or exceeds the quantity of concern;

(C) for combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity rule: ((amount of radionuclide A) / (quantity of concern of radionuclide A)) + ((amount of radionuclide B) / (quantity of concern of radionuclide B)) + etc.....> 1; and

(D) quantities of radioactive materials used to determine quantities of concern. The following table contains quantities of radioactive materials to be used in determining a quantity of concern.

Radionuclide	Quantity of Concern[1] (TBq)	Quantity of Concern[2] (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above[3]	See footnote below[4]	

[1] The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

[2] The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3] Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material. When transporting or storing sources on vehicles and/or trailers, the sources are automatically considered co-located.

[4] If several radionuclides are aggregated, the sum of the ratios of the activity of each source, *i* of radionuclide, *n*, A(*i*,*n*), to the quantity of concern for radionuclide *n*, Q(*n*), listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... >1

(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 agency 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 subsection 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 agency 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 agency for 5 years from the date of that service. 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.