

The Agency is seeking your input regarding the following noted suggested rule changes. These suggested changes are NOT final rule changes.

Legend: (Draft 2 Rule Changes)

Single Underline = Draft new language since Draft 1

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

Regular Print = Current language, including Draft 1 changes

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

§289.252. Licensing of Radioactive Material.

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

(1) (No change.)

(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) - (ii) (No change.)

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

(iv) (No change.)

(B) (No change.)

(3) (No change.)

(b) - (c) (No change.)

(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) - (6) (No change.)

(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, Title 22, Texas Administrative Code (TAC), Chapter 131.

(8) (No change.)

(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 United States Nuclear Regulatory Commission (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) (No change.)

(10) - (15) (No change.)

(e) (No change.)

(f) Radiation safety officer.

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

(3) The specific duties of the RSO include, but are not limited to, the following:

(A) - (K) (No change.)

(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) - (vi) (No change.)

(vii) signature of person performing the inventory;

(M) - (O) (No change.)

(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) - (B) (No change.)

(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) - (ii) (No change.)

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

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

(v) (No change.)

(D) (No change.)

(5) (No change.)

(g) (No change.)

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

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

(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) (3700 terabecquerels) 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 as required;

(C) - (D) (No change.)

(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) - (G) (No change.)

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

(2) The applicant shall provide reasonable assurance that:

(A) - (D) (No change.)

(3) - (5) (No change.)

(j) - (k) (No change.)

(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) - (6) (No change.)

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

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

(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) - (V) (No change.)

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

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

(VIII) include the date of receipt.

(ii) - (iv) (No change.)

(D) make and maintain records for inspection by the agency in accordance with subsection (mm) of this section, 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) the date of each commercial distribution;

(II) - (IV) (No change.)

(ii) (No change.)

(8) - (9) (No change.)

(m) - (o) (No change.)

(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 (MBq)) each;

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

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

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

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

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

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

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

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

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

(B) (No change.)

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

(q) (No change.)

(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) - (iv) (No change.)

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

(B) radionuclide data relating to the following:

(i) (No change.)

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

(iii) (No change.)

(C) labeling requirements including the following:

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

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

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

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

(ii) (No change.)

(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) - (B) (No change.)

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

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

(A) - (C) (No change.)

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

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

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

(i) - (v) (No change.)

(F) (No change.)

(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 in accordance with subsection (mm) of this section.

(4) (No change.)

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

(1) - (3) (No change.)

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

(A) - (F) (No change.)

(G) make and maintain 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 in accordance with subsection (mm) of this section 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) - (u) (No change.)

(v) Sealed source or device evaluation.

(1) (No change.)

(2) The request for review shall be sent to the agency [**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) - (5) (No change.)

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

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

(A) (No change.)

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

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

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

(9) After the SS & D certificate of 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 certificate of registration holder shall provide the information as requested.

(10) Inactivation of SS & D certificate(s) of registration [**registrations**].

(A) An SS & D certificate of registration holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular SS & D certificate of registration issued by the agency shall request inactivation of the SS & D certificate of registration. Such a request shall be made to the agency [**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 certificate of registration has ceased. However, if the SS & D certificate of registration holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the SS & D certificate of registration holder shall request inactivation of the SS & D certificate of registration within 90 days of this determination and briefly describe the circumstances of the delay.

(B) If a distribution license is to be terminated in accordance with subsection (y) of this section, the licensee shall request inactivation of its SS & D certificate of registration(s) associated with that distribution license before the agency will terminate the license. Such a request for inactivation of the SS & D certificate(s) of registration [**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 certificate of registration no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices shall be in accordance with any conditions in the SS & D certificate of registration, including in the case of an inactive SS & D certificate of registration.

(w) (No change.)

(x) Specific terms and conditions of licenses.

(1) - (5) (No change.)

(6) Each licensee shall notify the agency [**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) - (9) (No change.)

(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 make and maintain a record of the results of each test in accordance with subsection (mm) of this section for inspection by the agency.

(11) Licensees shall not hold radioactive waste, sources, or devices not authorized for disposal by decay in storage, and that are not in use for longer than 24 months following the last principal activity use. Sources and devices kept in standby for future use may be excluded from the 24 months time limit if the agency [**Radiation Safety Licensing Branch**] approves a plan for future use or an alternative disposal timeframe submitted by the licensee. Licensees shall submit plans at least 30 days prior to the end of the 24 months of nonuse.

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

(1) - (3) (No change.)

(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 a [**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) - (B) (No change.)

(C) no principal activities at an entire site 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) - (14) (No change.)

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

(A) (No change.)

(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) (No change.)

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

(z) - (bb) (No change.)

(cc) Transfer of material.

(1) - (5) (No change.)

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

(A) An application for a specific license to initially transfer source material for use under §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of an Agreement State, will be approved if:

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

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

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

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

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

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

(I) a copy of §289.251(f)(3)(A) of this title [subsection (f)(3)(A) of this section] or Title 10, CFR, §40.22; and this subsection or Title 10, CFR, §40.51; or relevant equivalent regulations of the agreement state; and

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

(iv) report transfers as follows:

(I) File a report with the agency and the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The report shall include the following information:

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

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

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

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

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

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

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

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

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

(-b-) if no transfers were made to persons generally licensed in accordance with §289.251(f)(3)(A) of this title [**subsection (f)(3)(A) of this section**]; Title 10, CFR, §40.22; or equivalent agreement state provisions during the current period, a report to the agency indicating so; and

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

(v) maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 5 years after the event is included in a report to the agency, the NRC, or to an agreement state agency.

(dd) (No change.)

(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) (No change.)

(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) - (v) (No change.)

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

(C) - (E) (No change.)

(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) - (v) (No change.)

(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:

(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) - (D) (No change.)

(3) (No change.)

(ff) (No change.)

(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) - (C) (No change.)

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

(2) (No change.)

(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) - (C) (No change.)

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

(4) - (6) (No change.)

(7) Each person licensed in accordance with this section shall make and maintain 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) - (D) (No change.)

(8) (No change.)

(hh) (No change.)

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

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

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

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

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

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

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

(A) General.

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

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

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

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

(C) Applicability.

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

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

(II) reviewing officials.

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

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

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

(3) Access authorization program requirements.

(A) Granting unescorted access authorization.

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

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

(B) Reviewing officials.

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

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

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

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

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

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

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

(C) Informed consent.

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

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

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

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

(D) Personal history disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any

personal history information required by paragraph (2), this paragraph, and paragraphs (4) - (8) of this subsection is sufficient cause for denial or termination of unescorted access.

(E) Determination basis.

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

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

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

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

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

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

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

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

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

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

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

(G) Right to correct and complete information.

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

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

(H) Records. The licensee shall make and maintain the following records/documents for inspection by the agency in accordance with subsection (mm) of this section. Superseded portions of the following records/documents shall be retained for inspection by the agency in accordance with subsection (mm) of this section:

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

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

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

(4) Background investigations.

(A) Initial investigation. Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation shall include at a minimum:

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

(ii) verification of true identity. Licensees shall:

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

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

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

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

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

(iii) employment history verification. Licensees shall:

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

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

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

(v) character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has

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

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

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

(B) Grandfathering.

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

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

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

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

(A) General performance objective and requirements.

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

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

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

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

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

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

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

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

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

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

(B) Prohibitions.

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

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

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

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

(C) Procedures for processing of fingerprint checks.

(i) For the purpose of complying with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, licensees shall use an appropriate method listed in Title 10, CFR, §37.7, to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, Maryland 20852-2738, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-301-415-7513, or by email to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(ii) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check

application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.)

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

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

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

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

(ii) a member of Congress;

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

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

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

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

(vii) agreement state employees conducting security inspections on behalf of the NRC under an agreement executed under Section 274.i. of the Atomic Energy Act;

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

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

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

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

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

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

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

(i) National Agency Check;

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

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

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

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

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

(7) Protection of information.

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

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

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

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

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

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

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

(8) Access authorization program review.

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

objectives and requirements. Each licensee shall review the access program content and implementation at least every 12 months.

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

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

(9) Security program.

(A) Applicability.

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

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

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

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

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

(10) General security program requirements.

(A) Security plan.

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

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

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

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

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

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

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

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

(B) Implementing procedures.

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

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

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

(C) Training.

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

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

(II) the responsibility to report promptly to the licensee any condition that causes or may cause a violation of the requirements of the agency, the NRC, any agreement state, or any licensing state;

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

(IV) the appropriate response to security alarms.

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

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

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

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

(III) relevant results of agency, NRC, agreement state, or licensing state inspections; and

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

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

(I) the dates of the training;

(II) the topics covered;

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

(IV) any related information.

(D) Protection of information.

(i) Except as provided in Title 10, CFR, §37.43(d)(9), licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

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

(iii) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(I) evaluate an individual's need to know the security plan or implementing procedures; and

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

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

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

(II) security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the

required background investigation in paragraph (4)(A)(ii) - (vii) of this subsection, has been provided by the security service provider.

(v) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

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

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

(II) take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(vii) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.

(viii) The licensee shall make and maintain record for inspection by the agency in accordance with subsection (mm) of this section which includes:

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

(II) the list of individuals approved for access to the security plan or implementing procedures.

(11) LLEA coordination.

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

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

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

(B) The licensee shall notify the agency, within 3 business days if:

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

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

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

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

(12) Security zones.

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

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

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

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

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

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

(D) For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for

unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

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

(13) Monitoring, detection and assessment.

(A) Monitoring and detection.

(i) Licensees shall:

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

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

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

(ii) Monitoring and detection shall be performed by:

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

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

(III) a monitored video surveillance system;

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

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

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

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

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

(-b-) continuous monitored video surveillance; or

(-c-) direct visual surveillance; and

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

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

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

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

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

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

(14) Maintenance and testing.

(A) Each licensee subject to paragraphs (9) - (13), this paragraph, and paragraphs (15) - (17) of this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when

needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no suggested manufacturer's suggested frequency, the testing shall be performed at least annually, not to exceed 12 months.

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

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

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

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

(C) Vehicles used to transport radioactive material quantities of concern, in which the quantity will be stored overnight, shall require alarms and vehicle disabling devices.

(1) Licenses shall test all vehicle alarms and disabling devices for proper operation:

(A) before leaving the licensed storage site; and

(B) immediately after securing the source at the end of the work shift and prior to ceasing constant surveillance of the vehicle.

(2) If alarms or disabling devices fail to operate properly when tested prior to departing the licensed storage site, proper operation shall be restored before departure. If alarms or disabling devices fail to operate properly when tested at the end of the work shift, an individual deemed trustworthy and reliable shall maintain constant surveillance of the vehicle.

(16) Security program review.

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

program content and implementation. Each licensee shall review the security program content and implementation at least every 12 months.

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

(i) Each review report shall:

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

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

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

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

(C) The licensee shall make and maintain the documentation of the review specified in paragraph (B) of this subparagraph for inspection by the agency in accordance with subsection (mm) of this section.

(17) Reporting of events.

(A) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency at 512-458-7460. In no case shall the notification to the agency be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

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

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

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

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

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

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

(i) The certification shall include:

(I) the license number;

(II) the current revision number;

(III) the issuing authority;

(IV) the expiration date; and

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

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

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

(D) The transferor shall keep a copy of the verification documentation specified in subparagraph (C) of this paragraph as a record for inspection by the agency in accordance with subsection (mm) of this section.

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

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

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

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

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

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

(II) identify safe havens; and

(iii) document the preplanning and coordination activities.

(B) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(C) Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(D) Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided in subparagraph (B) of this paragraph, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall make and maintain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for inspection by the agency in accordance with subsection (mm) of this section.

(21) Advance notification of shipment of category 1 quantities of radioactive material. As specified in subparagraphs (A) and (B) of this paragraph, each licensee shall provide advance notification to the NRC, and the governor of a state, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(A) Procedures for submitting advance notification.

(i) The notification shall be made to the NRC and to the office of each appropriate governor or governor's designee.

(I) The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC's Web site at <http://nrc-stp.ornl.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(II) Notifications to the NRC shall be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151.

(ii) A notification delivered by mail shall be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

(iii) A notification delivered by any means other than mail shall reach the NRC at least 4 days before the transport of the shipment commences and

(iv) A notification delivered by any means other than mail shall reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the state.

(B) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material shall contain the following information, if available at the time of notification:

(i) the name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

- (ii) the license numbers of the shipper and receiver;
- (iii) a description of the radioactive material contained in the shipment, including the radionuclides and quantity;
- (iv) the point of origin of the shipment and the estimated time and date that shipment will commence;
- (v) the estimated time and date that the shipment is expected to enter each state along the route;
- (vi) the estimated time and date of arrival of the shipment at the destination; and
- (vii) a point of contact, with a telephone number, for current shipment information.

(C) Revision notice.

(i) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(ii) A licensee shall notify the following of any changes to the information provided in accordance with subparagraphs (B) and (C)(i) of this paragraph.

(I) Immediately notify the governor of the state or the governor's designee.

(II) Immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(D) Cancellation notice.

(i) Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to:

(I) the governor of each state or to the governor's designee previously notified; and

(II) the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(ii) The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible.

(iii) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(E) Records. The licensee shall make and maintain a copy of the advance notification and any revision and cancellation notices as a record for inspection by the agency in accordance with subsection (mm) of this section.

(22) Requirements for physical protection of category 1 or category 2 quantities of radioactive material during shipment.

(A) Shipments by road.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies;

(II) ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(III) ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(IV) provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of

Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(V) develop written normal and contingency procedures to address:

(-a-) notifications to the communication center and law enforcement agencies;

(-b-) communication protocols shall include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(-c-) loss of communications; and

(-d-) responses to an actual or attempted theft or diversion of a shipment.

(ii) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(iii) Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(iv) Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(B) Shipments by rail.

(i) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

(I) ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(II) ensure that periodic reports to the communications center are made at preset intervals.

(ii) Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(II) use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(III) use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(C) Investigations.

(i) Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing.

(ii) Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

(23) Reporting of events.

(A) The shipping licensee shall notify the appropriate LLEA and the agency (512-458-7460) within one hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by paragraph (22)(C) of this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

(B) The shipping licensee shall notify the agency (512-458-7460) within 4 hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the agency.

(C) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency (512-458-7460) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

(D) The shipping licensee shall notify the agency (512-458-7460) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

(E) The shipping licensee shall notify the agency (512-458-7460) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

(F) The shipping licensee shall notify the agency (512-458-7460) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

(G) The initial telephonic notification required by subparagraphs (A) - (D) of this paragraph shall be followed within a period of 30 days by a written report submitted to the agency. A written report is not required for notifications on suspicious activities required by subparagraphs (C) and (D) of this paragraph. In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The report shall include the following information:

(i) a description of the licensed material involved, including kind, quantity, and chemical and physical form;

(ii) a description of the circumstances under which the loss or theft occurred;

(iii) a statement of disposition, or probable disposition, of the licensed material involved;

(iv) actions that have been taken, or will be taken, to recover the material; and

(v) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(H) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(24) Form of records. Each record required by this subsection shall be legible throughout the retention period specified in regulation by the licensing authority. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(25) Record retention. All records/documents referenced in this subsection shall be made and maintained by the licensee in accordance with subsection (mm) of this section for inspection by the agency. Upon completion of the appropriate retention time all records/documents shall be destroyed in a manner which protects the information from unauthorized disclosure.

(jj) Appendices.

(1) Subjects to be included in training courses:

(A) (No change.)

(B) radiation detection instrumentation to be used:

(i) (No change.)

(ii) survey techniques; and

(iii) (No change.)

(C) - (F) (No change.)

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

Figure: 25 TAC §289.252(jj)(2)

(3) (No change.)

(4) Criteria relating to use of financial tests and self guarantees for providing reasonable assurance of funds for decommissioning.

(A) (No change.)

(B) Financial test.

(i) (No change.)

(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) - (III) (No change.)

(iii) (No change.)

(C) (No change.)

(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) (No change.)

(B) Financial test.

(i) (No change.)

(ii) In addition, to pass the financial test, a company shall meet all of the following requirements:

(I) (No change.)

(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) (No change.)

(C) (No change.)

(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) (No change.)

(B) Financial test.

(i) To pass the financial test, a college or university shall meet the criteria of subclause (I) or (II) of this clause. The college or university shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) (No change.)

(ii) To pass the financial test, a hospital shall meet the criteria in subclause (I) or (II) of this clause. The hospital shall meet one of the following:

(I) for applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's or Aaa, Aa, or A as issued by Moody's; or

(II) for applicants or licensees that do not issue bonds, all the following tests shall be met:

(-a-) - (-c-) (No change.)

(-d-) operating revenues shall be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

(iii) In addition, to pass the financial test, a licensee shall meet all the following requirements:

(I) the licensee's independent certified public accountant shall have compared the data used by the licensee in the financial test that is required to be

derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the 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; and

(II) - (III) (No change.)

(C) Self-guarantee. The terms of a self-guarantee that an applicant or licensee furnishes shall provide the following.

(i) - (v) (No change.)

(7) Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release. The following table contains quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Figure: 25 TAC §289.252(jj)(7)

(8) Requirements for demonstrating financial qualifications.

(A) (No change.)

(B) If an applicant or licensee is required to submit financial assurance in accordance with subsection (gg) of this section, that applicant or licensee shall:

(i) submit one of the following:

(I) the bonding company report or equivalent (from which information can be obtained to calculate a ratio in clause (ii) of this subparagraph) that was used to obtain the financial assurance instrument used to meet the financial assurance requirement specified in subsection (gg) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial assurance specified in subsection (gg) of this section, the applicant or licensee shall demonstrate financial qualification by one of the methods specified in subclause (II) or (III) of this clause;

(II) Securities and Exchange Commission documentation (from which information can be obtained to calculate a ratio as described in clause (ii) of this subparagraph, if the applicant or licensee is a publicly-held company); or

(III) a self-test (for example, an annual audit report certifying a company's assets and liabilities and resulting ratio as described in clause (ii) of this

subparagraph or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues); and

(ii) (No change.)

(C) - (D) (No change.)

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

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

(C) for combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity rule: $((\text{amount of radionuclide A}) / (\text{quantity of concern of radionuclide A})) + ((\text{amount of radionuclide B}) / (\text{quantity of concern of radionuclide B})) + \text{etc.} \dots \geq 1$; 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.

Figure: 25 TAC §289.252(jj)(9)(D)

(kk) (No change.)

(ll) Specific licenses for installation, repair, or maintenance of devices containing sealed sources of radioactive material.

(1) (No change.)

(2) Each installation, repair, or maintenance activity shall be documented and a record maintained for inspection by the agency in accordance with subsection (mm) of this section. The record shall include the date, description of the service, initial survey results, and name(s) of the individual(s) who performed the work.

(3) (No change.)

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

Figure: 25 TAC §289.252(mm)

Figure: 25 TAC §289.252(jj)(2)

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

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

- * For combinations of radionuclides, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radionuclide authorized to the quantity listed for that radionuclide in this paragraph exceeds one. () indicates atomic number.
- ** Non CO forms only.
- *** Waste packaged in Type B containers does not require an emergency plan.

Figure: 25 TAC §289.252(jj)(9)(D)

<u>Radionuclide</u>	<u>Quantity of Concern¹ (TBq)</u>	<u>Quantity of Concern² (Ci)</u>
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

§289.252 Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Record/Document
(l)(7)(D)	Documentation of all receipts and transfers for the manufacture and commercial distribution of devices	3 years from the date of the event (i.e. receipt or transfer)
(r)(2)(C)	Records of tests and checks of measurements of the radioactivity of radioactive drugs	A minimum of 3 years
(r)(3)(G)	A complete description of any deviation from the manufacturer's instructions when eluting generators or processing radioactive materials with a reagent kit	3 years
(s)(4)(G)	Records showing the name, address, and point of contact for each general licensee to whom depleted uranium in products or devices is distributed	2 years
(x)(10)	Test results and records for generator eluates of molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination	3 years
(cc)(6)(B)(v)	All information supporting the report of a transfer of small quantities of source material	5 years after the transfer event is included in a report to the appropriate licensing authority
(gg)(7)	Records of information important to the safe and effective decommissioning of the facility	Until the license is terminated by the agency
(ii)(3)(G)	Confirmation of receipt of a notification to the individual of the right to complete, correct and explain any reasons for denial of personnel access authorization	1 year from the date of the notification
(ii)(3)(H)(i)	Documentation of the trustworthiness and reliability of individual employees	3 years from the date the individual employee no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(3)(H)(i)	Copy of the current access authorization procedures	3 years after the procedure is no longer needed
(ii)(3)(H)(ii)	Any portion(s) of the current access authorization procedures that are superseded	3 years after the procedure or any portion(s) of the procedure are superseded
(ii)(3)(H)(iii)	Current list of persons approved for unescorted access authorization	3 years after the list is superseded or replaced

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