

Legend: (Proposed Amendments)

Single Underline = Proposed new language

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

Regular Print = Current language

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

§289.201. General Provisions for Radioactive Material.

(a) (No change.)

(b) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

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

(3) Access control--A system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

(4) **[(3)]** Act--Texas Radiation Control Act, Health and Safety Code (HSC), Chapter 401.

(5) **[(4)]** Activity--The rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

(6) **[(5)]** Adult--An individual 18 or more years of age.

(7) **[(6)]** Agency--The Department of State Health Services.

(8) Aggregated--Accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

(9) **[(7)]** Agreement state--Any state with which NRC has entered into an effective agreement under §274b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(10) **[(8)]** Airborne radioactive material--Any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(11) **[(9)]** Airborne radioactivity area--A room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(A) in excess of the derived air concentrations (DACs) specified in Table I, Column 3 of §289.202(ggg)(2)(F) of this title (relating to Standards for Protection Against Radiation from Radioactive Materials); or

(B) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

(12) Approved individual--An individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with §289.252(ii)(2) - (8) of this title (relating to Licensing of Radioactive Material) and who has completed the training required by §289.252(ii)(10)(C) of this title.

(13) [(10)] As low as is reasonably achievable (ALARA)--Making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and licensed sources of radiation in the public interest.

(14) Background investigation--The investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

(15) [(11)] Background radiation--Radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from sources of radiation regulated by the agency.

(16) [(12)] Becquerel (Bq)--The International System of Units (SI) unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps). Commonly used multiples of the becquerel are the kBq (kilobecquerel, 10^3 Bq), MBq (megabecquerel, 10^6 Bq), GBq (gigabecquerel, 10^9 Bq), and TBq (terabecquerel, 10^{12} Bq). 1 Ci = 37 GBq.

(17) [(13)] Bioassay--The determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this chapter, "radiobioassay" is an equivalent term.

(18) [(14)] Brachytherapy--A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(19) [(15)] Byproduct material--Byproduct material is defined as:

(A) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(B) the tailings or wastes produced by or resulting from the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(C) any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(D) any material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(E) any discrete source of naturally occurring radioactive material, other than source material, that is extracted or converted after extraction before, on, or after August 8, 2005, for use in a commercial, medical, or research activity and that the United States NRC, in consultation with the Administrator of the United States Environmental Protection Agency (EPA), the United States Secretary of Energy, the United States Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security.

(20) Category 1 quantity of radioactive material--A quantity of radioactive material meeting or exceeding the category 1 threshold in §289.252(jj)(9) of this title. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(21) Category 2 quantity of radioactive material--A quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in §289.252(jj)(9) of this title. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(22) [(16)] Certificate of registration--A form of permission given by the agency to an applicant who has met the requirements for registration or mammography system certification set out in the Act and this chapter.

(23) [(17)] Certification of mammography systems (state certification)--A form of permission given by the agency to an applicant who has met the requirements for mammography system certification set out in the Act and this chapter.

(24) [(18)] Collective dose--The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(25) [(19)] Commercial--Having financial profit as the primary aim.

(26) [(20)] Committed dose equivalent ($H_{T,50}$)--The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(27) [(21)] Committed effective dose equivalent ($H_{E,50}$)--The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

(28) [(22)] Consortium--An association of medical use licensees and a Positron Emission Tomography (PET) radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium shall be located at an educational institution or a medical facility.

(29) [(23)] Constraint (dose constraint)--A value above which specified licensee actions are required.

(30) [(24)] Critical group--The group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(31) [(25)] Curie (Ci)--A unit of measurement of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie are the millicurie (mCi) and the microcurie (μ Ci). One mCi = 1×10^{-3} Ci = 3.7×10^7 dps. One μ Ci = 1×10^{-6} Ci = 3.7×10^4 dps. One nanocurie (nCi) = 1×10^{-9} Ci = 3.7×10^1 dps. One picocurie (pCi) = 1×10^{-12} Ci = 3.7×10^{-2} dps.

(32) [(26)] Decommission--To remove a facility or site safely from service and reduce residual radioactivity to a level that permits the following:

(A) release of the property for unrestricted use and/or termination of license; or

(B) release of the property under alternate requirements for license termination.

(33) [(27)] Deep dose equivalent (H_d), that applies to external whole body exposure--The dose equivalent at a tissue depth of 1 centimeter (cm) (1,000 milligrams per square centimeter (mg/cm^2)).

(34) [(28)] Depleted uranium--The source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(35) [(29)] Discrete source--A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(36) [(30)] Distinguishable from background--The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or, in the case of structures or equipment, in similar materials using adequate measurement technology, survey, and statistical techniques.

(37) [(31)] Distribution--The physical conveyance and authorized transfer of commodities from producers to consumers and any intermediate persons involved in that conveyance.

(38) Diversion--The unauthorized movement of radioactive material subject to §289.252(ii) of this title to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

(39) [(32)] Dose--A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

(40) [(33)] Dose equivalent (H_T)--The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(41) [(34)] Dose limits--The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this chapter, "limits" is an equivalent term.

(42) [(35)] Effective dose equivalent (H_E)--The sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) [(w_T)] applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$) [($H_E = \sum w_T H_T$)].

(43) [(36)] Embryo/fetus--The developing human organism from conception until the time of birth.

(44) [(37)] Entrance or access point--Any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed sources of radiation. This includes portals of sufficient size to permit human access, irrespective of their intended use.

(45) Escorted access--Accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

(46) [(38)] Exposure--The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(47) [(39)] Exposure rate--The exposure per unit of time.

(48) [(40)] External dose--That portion of the dose equivalent received from any source of radiation outside the body.

(49) [(41)] Extremity--Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(50) Fingerprint orders--The orders issued by the NRC or the legally binding requirements issued by agreement states that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

(51) [(42)] Generally applicable environmental radiation standards--Standards issued by the EPA under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(52) [(43)] Gray (Gy)--The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

(53) [(44)] High radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(54) [(45)] Human use--The internal or external administration of radiation or radioactive material to human beings for healing arts purposes or research and/or development specifically authorized by the agency.

(55) [(46)] Individual--Any human being.

(56) [(47)] Individual monitoring--The assessment of:

(A) dose equivalent to an individual by the use of individual monitoring devices; or

(B) committed effective dose equivalent to an individual by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition for DAC-hours in §289.202(c) of this title); or

(C) dose equivalent to an individual by the use of survey data.

(57) [(48)] Individual monitoring devices--Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this chapter, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), electronic personal dosimeters, and personal air sampling devices.

(58) [(49)] Inspection--An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the agency.

(59) [(50)] Internal dose--That portion of the dose equivalent received from radioactive material taken into the body.

(60) [(51)] Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(61) [(52)] Land disposal facility--The land, buildings, and equipment that are intended to be used for the disposal of low-level radioactive waste (LLRW) into the subsurface of the land.

(62) [(53)] Lens dose equivalent--The external dose equivalent to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm²).

(63) [(54)] License--A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(64) [(55)] Licensed material--Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(65) [(56)] Licensee--Any person who is licensed by the agency in accordance with the Act and this chapter.

(66) [(57)] Licensing state--Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc. For the purposes of evaluation and/or distribution of sealed sources, this includes Licensing State Status: Product Review Only.

(67) Local law enforcement agency (LLEA)--A public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

(68) [(58)] Lost or missing radioactive material--Radioactive material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(69) [(59)] Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(i) discarded or unwanted and is not exempt by rule adopted under the Texas Radiation Control Act (Act), HSC [Health and Safety Code], §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR, §61.55, or compatible rules adopted by the agency or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10, CFR, or established by the agency or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined by Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined by Title 10, CFR, §72.3;

(iii) byproduct material defined in the Act, HSC [Health and Safety Code], §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries per gram.

(70) [(60)] Manufacture--To fabricate or mechanically produce.

(71) [(61)] Member of the public--Any individual, except when that individual is receiving an occupational dose.

(72) [(62)] Minor--An individual less than 18 years of age.

(73) Mobile device--A piece of equipment containing licensed radioactive material that either is mounted on a permanent base with wheels and/or casters, or otherwise equipped for moving while completely assembled and without dismounting; or is a portable device. Mobile devices do not include stationary equipment installed in a fixed location.

(74) [(63)] Monitoring--The measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(75) Movement control center--An operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

(76) [(64)] NARM--Any naturally occurring or accelerator-produced radioactive material except source material or special nuclear material.

(77) [(65)] Natural radioactivity--Radioactivity of naturally occurring nuclides whose location and chemical and physical form have not been altered by man.

(78) No-later-than arrival time--The date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

(79) [(66)] NRC--The United States Nuclear Regulatory Commission or its duly authorized representatives.

(80) [(67)] Occupational dose--The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, from voluntary participation in medical research programs, or as a member of the public.

(81) [(68)] Particle accelerator--Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and designed to discharge the resultant particulate or other associated radiation at energies usually in excess of 1 million electron volts (MeV) [MeV].

(82) [(69)] Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than NRC, and other than federal government agencies licensed or exempted by NRC.

(83) [(70)] Personnel monitoring equipment (See definition for individual monitoring devices.)

(84) [(71)] Pharmacist--An individual licensed by the Texas State Board of Pharmacy to compound and dispense drugs, prescriptions, and poisons.

(85) [(72)] Physician--An individual licensed by the Texas Medical Board.

(86) Portable device--A piece of equipment containing licensed radioactive material that is designed by the manufacturer to be hand carried during use.

(87) [(73)] Positron emission tomography (PET) radionuclide production facility-- A facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(88) [(74)] Principal activities--Activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(89) [(75)] Public dose--The dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee/registrant. It does not include occupational dose or doses received from

background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, or from voluntary participation in medical research programs.

(90) [(76)] Quality factor (Q)--The modifying factor listed in subsection (n)(1) and (2) of this section that is used to derive dose equivalent from absorbed dose.

(91) [(77)] Quarter (calendar quarter)--A period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(92) [(78)] Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 Gy [**gray**]).

(93) [(79)] Radiation--One or more of the following:

(A) gamma and x rays; alpha and beta particles and other atomic or nuclear particles or rays;

(B) emission of radiation from any electronic device to such energy density levels as to reasonably cause bodily harm; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(94) [(80)] Radiation area--Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 cm from the source of radiation or from any surface that the radiation penetrates.

(95) [(81)] Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(96) [(82)] Radiation safety officer (RSO)--An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who must be specifically authorized on a radioactive material license, and who is the primary contact with the agency. Specific training and responsibilities for an RSO are listed in §289.252 of this title [(relating to Licensing of Radioactive Material)], §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), and §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material).

(97) [(83)] Radioactive material--Any material (solid, liquid, or gas) that emits radiation spontaneously.

(98) [(84)] Radioactive waste--For purposes of this chapter, this term is equivalent to LLRW.

(99) [(85)] Radioactivity--The disintegration of unstable atomic nuclei with the emission of radiation.

(100) [(86)] Radiobioassay (See definition for bioassay.)

(101) [(87)] Registrant--Any person issued a certificate of registration by the agency in accordance with the Act and this chapter.

(102) [(88)] Regulation (See definition for rule.)

(103) [(89)] Regulations of the United States Department of Transportation (DOT)--The requirements in Title 49, CFR, Parts 100 - 189.

(104) [(90)] Rem--The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert (Sv)).

(105) [(91)] Research and development--Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(106) [(92)] Residential location--Any area where a structure or structures are located in which people lodge or live, and the grounds on which these structures are located including, but not limited to, houses, apartments, condominiums, and garages.

(107) [(93)] Residual radioactivity--The radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Title 10, CFR, Part 20.

(108) [(94)] Restricted area--An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to sources of

radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(109) Reviewing official--The individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

(110) [(95)] Roentgen (R)--The special unit of exposure. One roentgen (R) equals 2.58×10^{-4} C/kg of air. (See definition for exposure.)

(111) [(96)] Rule (as defined in the Government Code, Chapters 2001 and 2002, as amended)--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(112) Sabotage--The deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

(113) Safe haven--A readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

(114) [(97)] Sealed source--Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material.

(115) Security zone--Any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material.

(116) [(98)] Shallow dose equivalent (H_s) (that applies to the external exposure of the skin of the whole body or the skin of an extremity)--The dose equivalent at a tissue depth of 0.007 cm (7 mg/cm^2).

(117) [(99)] SI--The abbreviation for the International System of Units.

(118) [(100)] Sievert--The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(119) [(101)] Site boundary--That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(120) [(102)] Source material--Source material is defined as:

(A) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(B) ores that contain by weight 0.05% or more of uranium, thorium, or any combination thereof; and

(C) does not include special nuclear material.

(121) [(103)] Source of radiation--Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(122) [(104)] Special form radioactive material--Radioactive material that satisfies the following conditions.

(A) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(B) The piece or capsule has at least one dimension not less than 5 millimeters (mm) (0.2 inch); and

(C) It satisfies the requirements specified by NRC. A special form encapsulation designed in accordance with NRC requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with NRC requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet the requirements of this definition applicable at the time of its design or construction.

(123) [(105)] Special nuclear material--Special nuclear material is defined as:

(A) plutonium (Pu), uranium-233 (U-233), uranium enriched in the isotope 233 or in the isotope 235, and any other material that NRC, in accordance with the provisions of the Atomic Energy Act of 1954, §51 as amended, determines to be special nuclear material, but does not include source material; or

(B) any material artificially enriched by any of the foregoing, but does not include source material.

(124) [(106)] Special nuclear material in quantities not sufficient to form a critical mass--Uranium enriched in the isotope 235 in quantities not exceeding 350 grams (g) of contained uranium-235; uranium-233 in quantities not exceeding 200 g; plutonium in quantities not exceeding 200 g; or any combination of them in accordance with the following formula.

(A) For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity).

(B) For example, the following quantities in combination would not exceed the limitation and are within the formula:

Figure: 25 TAC §289.201(b)(124)(B) [Figure: 25 TAC §289.201(b)(106)(B)]

(125) [(107)] Special units--The conventional units historically used by licensees, for example, curie (activity), rad (absorbed dose), and rem (dose equivalent).

(126) Stationary device--A piece of equipment containing licensed radioactive material that is installed in a fixed location.

(127) [(108)] Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of materials and equipment, measurements of levels of radiation or concentration of radioactive material present, and evaluation of administrative and/or engineered controls.

(128) Telemetric position monitoring system--A data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

(129) [(109)] Termination--A release by the agency of the obligations and authorizations of the licensee under the terms of the license. It does not relieve a person of duties and responsibilities imposed by law.

(130) [(110)] Test--A method of determining the characteristics or condition of sources of radiation or components thereof.

(131) [(111)] Texas Regulations for Control of Radiation (TRCR)--All sections of Title 25, TAC, Chapter 289.

(132) [(112)] Total effective dose equivalent (TEDE)--The sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(133) [(113)] Total organ dose equivalent (TODE)--The sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in §289.202(rr)(1)(F) of this title.

(134) [(114)] Transport index--The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

(A) For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour (mSv/hr) at 1 meter (m) (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour (mrem/hr) at 1 m (3.3 feet); or

(B) For fissile material packages, the number determined by multiplying the maximum radiation level in mSv/hr at 1 m (3.3 feet) from the external surface of the package by 100 (equivalent to the maximum radiation level in mrem/hr at 1 m (3.3 feet), or, for criticality control purposes, the number obtained as described in Title 10, CFR, §71.59 whichever is larger.

(135) Trustworthiness and reliability--Characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

(136) [(115)] Type A quantity--A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in §289.257(ee) of this title (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(ee) of this title.

(137) [(116)] Type B quantity--A quantity of radioactive material greater than a type A quantity.

(138) Unescorted access--Solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

(139) [(117)] Unrefined and unprocessed ore-- Ore in its natural form prior to any processing, such as grinding, roasting or [,] beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

(140) [(118)] Unrestricted area (uncontrolled area)--An area, or access to, which is neither limited nor controlled by the licensee. For purposes of this chapter, "uncontrolled area" is an equivalent term.

(141) [(119)] Very high radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 Gy [grays] in one hour at 1 meter (m) from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, Sv and rem.

(142) [(120)] Veterinarian--An individual licensed by the Texas State Board of Veterinary Medical Examiners.

(143) [(121)] Waste--Low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraph (19)(B) - (E) **[paragraph (15)(B) - (E)]** of this subsection.

(144) [(122)] Week--Seven consecutive days starting on Sunday.

(145) [(123)] Whole body--For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(146) [(124)] Worker--An individual engaged in work under a license or certificate of registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

(147) [(125)] Working level (WL)--Any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV **[million electron volts (MeV)]** of potential alpha particle energy. The short-lived radon daughters are-- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(148) [(126)] Working level month (WLM)--An exposure to one working level for 170 hours--2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

(149) [(127)] Year--The period of time beginning in January used to determine compliance with the provisions of this chapter. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(c) - (f) (No change.)

(g) Tests for leakage and/or contamination of sealed sources.

(1) The licensee in possession of any sealed source shall assure that:

(A) each sealed source, except as specified in paragraph (2) of this subsection and §289.253(i) of this title **[(relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies)]**, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 **[six]** months before transfer to the licensee;

(B) each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 [six] months or at alternative intervals approved by the agency, the [or by] NRC, or any [an] agreement state, or a licensing state after evaluation of information specified in §289.252(v) of this title or equivalent regulations of the NRC or any agreement state;

(C) each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 [three] months or at alternative intervals approved by the agency, the NRC, or any agreement state after evaluation of information specified in §289.252(v) of this title, or equivalent regulations of the [by] NRC, or any [an] agreement state, or a licensing state;

(D) - (F) (No change.)

(G) tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter that has a half-life greater than 4 [four] days; and

(H) tests for leakage or contamination shall be performed using a leak test kit or method approved by the agency, the NRC, or any [an] agreement state, or a licensing state.

(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

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

(C) sealed sources containing 100 μCi (3.7 MBq [megabecquerels (MBq)]) or less of beta or gamma-emitting material or 10 μCi (370 kBq [kilobecquerels (kBq)]) or less of alpha or neutron-emitting material;

(D) - (F) (No changes.)

(3) Analysis of tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, the NRC, or any [an] agreement state, [or a licensing state,] to perform such services.

(4) (No change.)

(5) The following shall be considered evidence that a sealed source is leaking:

(A) the presence of 0.005 μCi (185 becquerels [Bq]) or more of removable contamination on any test sample;

(B) - (C) (No change.)

(6) - (7) (No change.)

(h) - (j) (No change.)

(k) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be addressed to Radiation Control, Department of State Health Services, **[1100 West 49th Street,]** P.O. Box 149347, Austin, Texas, 78714-9347. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) Documents transmitted to the agency will be deemed submitted on the date of the postmark, facsimile **[telegram, telefacsimile]**, or other electronic media transmission.

(l) (No change.)

(m) Open records.

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

(4) Requests for information.

(A) All requests for open records information must be in writing and refer to documents currently in possession of the agency.

(B) - (C) (No change.)

(n) (No change.)

(o) Units of activity. For purposes of this chapter, activity is expressed in the special unit of curie (Ci), (Bq), or its multiples, or disintegrations or transformations per second (dps or tps).

(1) $1 \text{ Ci} = 3.7 \times 10^{10} \text{ dps or tps} = 3.7 \times 10^{10} \frac{\text{Bq}}{1000} = 2.22 \times 10^{12}$ disintegrations or transformations per minute (dpm or tpm).

(2) (No change.)

Figure: 25 TAC §289.201(b)(124)(B)

$$\frac{175 (\text{grams contained U} - 235)}{350} + \frac{50 (\text{grams U} - 233)}{200} + \frac{50 (\text{grams Pu})}{200} = 1$$

§289.202. Standards for Protection Against Radiation from Radioactive Materials.

(a) - (d) (No change.)

(e) Radiation protection programs.

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

(4) To implement the ALARA requirement in paragraph (2) of this subsection and notwithstanding the requirements in subsection (n) of this section, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 10 millirems (mrem) (0.1 millisievert (mSv)) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as required in subsection (yy) of this section and promptly take appropriate corrective action to ensure against recurrence.

(5) (No change.)

(f) - (i) (No change.)

(j) Determination of occupational dose for the current year.

(1) (No change.)

(2) In complying with the requirements of paragraph (1) of this subsection, a licensee may:

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

(C) obtain reports of the individual's dose equivalent from prior or other current employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, **[telegram,]** facsimile, **[or]** letter, or other electronic media transmission. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(3) (No change.)

(4) If the licensee is unable to obtain a complete record of an individual's current occupational dose while employed by any other licensee, the licensee shall assume in establishing administrative controls in accordance with subsection (f)(7) of this section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv **[millisieverts (mSv)]**) for each quarter; or 416 mrem (4.16 mSv) for each month for which

records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) - (6) (No change.)

(k) Planned special exposures. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in subsection (f) of this section provided that each of the following conditions is satisfied.

(1) - (4) (No change.)

(5) In complying with the requirements of paragraph (4)(C) of this subsection, a licensee may:

(A) (No change.)

(B) obtain reports of the individual's dose equivalent from prior employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, **[telegram,]** facsimile, **[or]** letter_or other electronic media transmission. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(6) - (9) (No change.)

(l) (No change.)

(m) Dose equivalent to an embryo/fetus.

(1) (No change.)

(2) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (1) of this subsection. The National Council on Radiation Protection and Measurements (NCRP) recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987), that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

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

(n) - (o) (No change.)

(p) General surveys and monitoring.

(1) (No change.)

(2) In addition to subsection (nn) of this section, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site shall be kept with records important for decommissioning, and such records shall be maintained and retained in accordance with §289.252(gg) of this title (relating to Licensing of Radioactive Material).

(3) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are operable and calibrated:

(A) by a person licensed or registered by the agency, **[another agreement state, a licensing state, or]** the United States Nuclear Regulatory Commission (NRC), or any agreement state to perform such service;

(B) - (E) (No change.)

(4) - (5) (No change.)

(q) - (x) (No change.)

(y) Security and control of licensed sources of radiation.

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

(4) Utilization records shall be maintained for portable and mobile devices which contain radioactive material, and which are transported from a licensed site temporarily for use by the licensee and then returned to the licensed site of origin. The information required by subparagraphs (A) - (D) of this paragraph shall be recorded when a device is removed from the licensed site. The information in subparagraph (E) of this paragraph shall be recorded when a device is returned to the licensed site:

(A) the manufacturer, model, and serial number of the device;

(B) the name of the individual(s) transporting and using the device;

(C) the location(s) where each device is used;

(D) the date each device is removed from storage; and

(E) the date each device is returned to storage.

(5) Utilization records shall be maintained at the licensed site where the devices are stored for inspection by the agency in accordance with subsection (ggg)(5) of this section.

(z) - (cc) (No change.)

(dd) Exemptions to labeling requirements. A licensee is not required to label:

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

(4) containers when they are in transport and packaged and labeled in accordance with the rules of the DOT (labeling of packages containing radioactive materials is required by the DOT if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations Title 49, CFR, §§173.403(m) and (w) and 173.424);

(5) - (6) (No change.)

(ee) Procedures for receiving and opening packages.

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in §289.201(b) of this title (relating to General Provisions for Radioactive Material) and specified in §289.257(ee) of this title (relating to Packaging and Transportation of Radioactive Material), shall make arrangements to receive:

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

(2) Each licensee shall:

(A) (No change.)

(B) monitor the external surfaces of a labeled package, labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49, CFR, §§172.403 and 172.436 - 440, for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in §289.201(b) of this title and specified in §289.257(ee) of this title; and

(C) (No change.)

(3) (No change.)

(4) The licensee shall immediately notify the final delivery carrier and, by telephone [**and telegram, mailgram**], [**or**] facsimile, or other electronic media transmission, the agency when removable radioactive surface contamination or external radiation levels exceed the limits established in subparagraphs (A) and (B) of this paragraph.

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

(5) - (6) (No change.)

(ff) General requirements for waste management.

(1) Unless otherwise exempted, a licensee shall discharge, treat, or decay licensed material or transfer waste for disposal only:

(A) by transfer to an authorized recipient as provided in subsection (jj) of this section, §289.252 of this title **[(relating to Licensing of Radioactive Material)]**, §289.257 of this title, §289.259 of this title, or to the United States Department of Energy (DOE);

(B) (No change.)

(C) by release in effluents within the limits in subsection (n) of this section in accordance with the applicable requirements of the Texas Commission on Environmental Quality (TCEQ) or the Railroad Commission of Texas (RRC); [or]

(D) as authorized in accordance with paragraph (2) of this subsection, and subsections (gg), (hh), and (fff) of this section; or [.]

(E) by transfer of residual radiopharmaceutical waste for decay in storage only to persons who manufactured, compounded, and supplied the radiopharmaceutical and who otherwise meet the requirements for exemption under Title 30, Texas Administrative Code (TAC), §336.1209.

(2) Upon agency approval, emission control dust and other material from electric arc furnaces or foundries contaminated as a result of inadvertent melting of cesium-137 or americium-241 sources may be transferred for disposal to a hazardous waste disposal facility authorized by TCEQ [the Texas Commission on Environmental Quality (Commission)] or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under Subtitle C of the Resource Conservation and Recovery Act (RCRA), or the EPA. The material may be transferred for disposal without regard to its radioactivity if the following conditions are met.

(A) - (I) (No change.)

(J) The licensee transferring the cesium-137 or americium-241 contaminated incident-related material shall consult with the agency, the TCEQ [Commission] or its successor, another state's regulatory agency with jurisdiction to regulate hazardous waste as classified under RCRA, or the EPA and other authorized parties, including state and local governments, and obtain all necessary approvals, in addition to those of the NRC and/or any [appropriate] agreement state [states], for the transfers described in paragraph (2) of this subsection.

(K) (No change.)

(L) The total incident-related cesium-137 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 1 Ci (37 gigabecquerels (GBq)). The total incident-related americium-241 activity described in paragraph (2) of this subsection received by a facility over its operating life shall not exceed 30 mCi (1.11

GBq [megabequerels (MBq)]). The agency will maintain a record of the total incident-related cesium-137 or americium-241 activity shipped by a person licensed by the agency. Upon consultation with the TCEQ [Commission], the agency will determine if the total incident-related activity received by a hazardous waste disposal facility over its operating life has reached 1 Ci (37 GBq) of cesium-137 or 30 mCi (1.11 GBq [MBq]) of americium-241. The agency will not approve shipments of cesium-137 or americium-241 contaminated incident-related material that will cause this limit to be exceeded.

(3) Radioactive waste exempted by TCEQ for disposal in a hazardous waste disposal facility that holds a TCEQ permit issued under Subtitle C of the RCRA may be transferred for disposal as authorized by TCEQ.

(4) [(3)] A person shall be specifically licensed to receive waste containing licensed material from other persons for:

(A) treatment prior to disposal;

(B) treatment by incineration;

(C) decay in storage;

(D) disposal at an authorized land disposal facility; or

(E) storage until transferred to a storage or disposal facility authorized to receive the waste.

(5) [(4)] Byproduct material as defined in §289.201(b)(19)(C) - (E) ~~§289.201(b)(15)(C) - (E)~~ of this title may be disposed of in accordance with Title 10, CFR, Part 61, even though it is not defined as low level radioactive waste. Therefore, any byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under Title 10, CFR, Part 61, shall meet the requirements of this chapter.

Formatted: Font: Bold

(6) [(5)] A licensee may dispose of byproduct material, as defined in §289.201(b)(19)(C) - (E) ~~§289.201(b)(15)(C) - (E)~~ of this title, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law.

(7) [(6)] Any licensee shipping byproduct material as defined in §289.201(b)(19)(C) - (E) ~~§289.201(b)(15)(C) - (E)~~ of this title intended for ultimate disposal at a land disposal facility licensed under Title 10, CFR, Part 61, shall document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with §289.257(gg) of this title.

(gg) - (ll) (No change.)

(mm) Records of radiation protection programs.

(1) (No change.)

(2) The licensee shall make, maintain, and retain the records required by paragraphs (1)(A) and (1)(B) [paragraph (1)(A)] of this subsection for inspection by the agency in accordance with subsection (ggg)(5) of this section. [until the agency terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (1)(B) of this subsection for three years after the record is made.]

(nn) Records of surveys.

(1) Each licensee shall make, maintain, and retain records documenting [showing] the results of surveys and calibrations required by subsections (p) and (ee)(2) of this section and include a unique identification of survey instrument(s). The licensee shall maintain [retain] these records for inspection by the agency in accordance with subsection (ggg)(5) of this section [for three years after the record is made].

(2) Record of the calibration shall include:

(A) the manufacturer's name, model and serial number of each calibrated source and/or device;

(B) the complete date of the calibration; and

(C) the name of the individual recording the information.

(3) [(2)] The licensee shall make, maintain, and retain each of the following records for inspection by the agency in accordance with subsection (ggg)(5) of this section [until the agency terminates each pertinent license requiring the record]:

(A) the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

(B) the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

(C) the results of air sampling, surveys, and bioassays required in accordance with subsection (x)(1)(C)(i) and (ii) of this section; and

(D) the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(oo) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by §289.201(g) of this title shall be kept in

Formatted: Underline

Formatted: Underline

Formatted: Underline

units of becquerel or microcurie and maintained and retained for inspection by the agency in accordance with subsection (ggg)(5) of this section **[for five years after the records are made]**.

(pp) Records of lifetime cumulative occupational radiation dose. The licensee shall make, maintain, and retain the records of lifetime cumulative occupational radiation dose as specified in subsection (k) of this section on RC Form 202-2 or equivalent and the **[until the agency terminates each pertinent license requiring this record. The licensee shall retain]** records used in preparing RC Form 202-2 or equivalent for inspection by the agency in accordance with subsection (ggg)(5) of this section **[for three years after the record is made]**.

(qq) - (vv) (No change.)

(ww) Reports of stolen, lost, or missing licensed sources of radiation.

(1) (No change.)

(2) Each licensee required to make a report in accordance with paragraph (1) of this subsection shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

(A) a description of the licensed source of radiation involved, including, for radioactive material, the kind, quantity, **[and]** chemical and physical form, source and/or device manufacturer, model number, and serial number;

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

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

(xx) Notification of incidents.

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

(3) Licensees shall make the initial notification reports required by paragraphs (1) and (2) of this subsection by telephone to the agency and shall confirm the initial notification report within 24 hours by **[telegram, mailgram, or]** facsimile or other electronic media transmission to the agency.

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

(7) Each licensee shall notify the agency within 24 hours after the discovery of any of the following events involving radioactive material:

(A) an unplanned contamination event that:

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

(iii) has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination; [.]

(B) - (D) (No change.)

(8) Preparation and submission of reports. Reports made by licensees in response to the requirements of paragraphs (6) and (7) of this subsection shall be made as follows.

(A) Licensees shall make reports required by paragraphs (6) and (7) of this subsection by telephone to the agency. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

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

(iv) the isotopes, quantities, and chemical and physical form of the radioactive material involved; **[and]**

(v) any personnel radiation exposure data available; and [.]

(vi) the source and/or device manufacturer, model, and serial number.

(B) Each licensee who makes a report required by paragraphs (6) and (7) of this subsection shall submit to the agency a written follow-up report within 30 days of the initial report. Written reports prepared in accordance with other requirements of this chapter may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. The reports must include the following:

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

(iii) the isotopes, quantities, **[and]** chemical and physical form of the radioactive material involved, and the source and/or device manufacturer, model number, and serial number;

(iv) - (vi) (No change.)

(yy) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits.

(1) In addition to the notification required by subsection (xx) of this section, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

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

(D) for licensees subject to the provisions of the EPA's generally applicable environmental radiation standards in Title 40, CFR, §190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those requirements.

(2) Each report required by paragraph (1) of this subsection shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(A) (No change.)

(B) the levels of radiation, dose limit exceeded, **[and]** concentrations of radioactive material involved, and the source and/or device manufacturer, model number, and serial number;

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

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

(zz) - (aaa) (No change.)

(bbb) Reports of leaking or contaminated sealed sources. The licensee shall immediately notify the agency if the test for leakage or contamination required in accordance with §289.201(g) of this title indicates a sealed source is leaking or contaminated. A written report of a leaking or contaminated source shall be submitted to the agency within 5 [five] days. The report shall include the equipment involved, including the device manufacturer, model and serial number; the test results; [,] the date of the test; [,] model and serial number; [,] if assigned, of the leaking source, the radionuclide and its estimated activity; [,] and the corrective action taken.

(ccc) (No change.)

(ddd) Radiological requirements for license termination.

(1) (No change.)

(2) Radiological requirements for unrestricted use. **[(A)]** A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels that are ALARA shall take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(3) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

(A) the licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the requirements of paragraph (2) of this subsection would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA shall take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal:

(B) the licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year:

(C) [(B)] the [The] licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(i) funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1% real rate of return on investment;

(ii) a statement of intent in the case of federal, state, or local government licensees, as described in §289.252(gg) of this title; or

(iii) when a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(D) [(C)] the [The] licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with §289.252(y) of this title, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(i) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(I) whether provisions for institutional controls proposed by the licensee;

(-a-) will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(-b-) will be enforceable; and

(-c-) will not impose undue burdens on the local community or other affected parties; and

(II) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(ii) In seeking advice on the issues identified in clause (i) of this subparagraph, the licensee shall provide for:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(E) ~~[(D)] residual [Residual]~~ radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either:

(i) 100 mrem (1 mSv) per year; or

(ii) 500 mrem (5 mSv) per year provided the licensee:

(I) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of clause (i) of this subparagraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(II) makes provisions for durable institutional controls; and

(III) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of paragraph (2) of this subsection [subparagraph (A) of this paragraph] and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in subparagraph (C) ~~[(B)]~~ of this paragraph.

(4) [(3)] Alternate requirements for license termination.

(A) The agency may terminate a license using alternate requirements greater than the dose requirements specified in paragraph (2) of this subsection if the licensee does the following:

(i) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv per year (100 mrem per year) limit specified in subsection (o) of this section, by submitting an analysis of possible sources of exposure;

(ii) reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;

(iii) has submitted a decommissioning plan to the agency indicating the licensee's intent to decommission in accordance with the requirements in §289.252(y) of this title, and specifying that the licensee proposes to decommission by use of alternate requirements. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for the following:

(I) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(II) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(III) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(iv) has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate requirements to terminate a license requires the approval of the agency after consideration of the agency's recommendations that will address any comments provided by the EPA and any public comments submitted in accordance with paragraph **(5) [(4)]** of this subsection.

(5) [(4)] Public notification and public participation. Upon receipt of a decommissioning plan from the licensee, or a proposal from the licensee for release of a site pursuant to **[in accordance with] paragraphs (3) and (4) [paragraph (3)]** of this subsection, or

whenever the agency deems such notice to be in the public interest, the agency will do the following:

(A) notify and solicit comments from the following:

(i) local and state governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(ii) the EPA for cases where the licensee proposes to release a site in accordance with paragraph ~~(4)~~ **[(3)]** of this subsection; and

(B) publish a notice in the *Texas Register* and a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

~~(6)~~ **[(5)]** Minimization of contamination.

(A) Applicants for licenses, other than renewals, after October 1, 2000, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of LLRW.

(B) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements and radiological criteria for license termination in this subsection.

(eee) (No change.)

(fff) Exemption of specific wastes.

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

(4) Any licensee may, upon agency approval of procedures required in paragraph (6) of this subsection, discard licensed material included in subsection (ggg)(7) of this section, provided that it does not exceed the concentration and total curie limits contained therein, in a Type I municipal solid waste site as defined in the Municipal Solid Waste Regulations of the authorized regulatory agency (Title 30, Texas Administrative Code, Chapter 330), unless such licensed material also contains hazardous waste, as defined in §361.003(12) of the Solid Waste Disposal Act, Health and Safety Code, Chapter 361. Any licensed material included in subsection (ggg)(7) of this section and which is a hazardous waste as defined in the Solid Waste Disposal Act may be discarded at a facility authorized to manage hazardous waste by the authorized regulatory agency.

(5) - (9) (No change.)

(ggg) Appendices.

(1) (No change.)

(2) Annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage.

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

(C) Effluent concentrations.

(i) - (iv) (No change.)

(v) The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7 . The factor of 7.3×10^7 milliliters (ml) includes the following components:

(I) (No change.)

(II) a factor of 7.3×10^5 ml [(ml)] which is the annual water intake of "Reference Man."

(vi) (No change.)

(D) Releases to sewers. The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in subsection (gg) of this section. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 ml [(ml)]. The factor of 7.3×10^6 ml [(ml)] is composed of a factor of 7.3×10^5 ml [(ml)], the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a "Reference Man" during a year, would result in a committed effective dose equivalent of 0.5 rem.

(E) (No change.)

(F) Tables--Values for annual limits. The following tables contain values for annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage:

Figure: 25 TAC §289.202(ggg)(2)(F) [Figure: 25 TAC §289.202(ggg)(2)(F)]

(3) (No change.)

(4) Classification and characteristics of low-level radioactive waste (LLRW).

(A) Classification of radioactive waste for land disposal.

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

(iii) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in subclause (V) of this clause, classification shall be determined as follows.

(I) - (IV) (No change.)

(V) Classification table for long-lived radionuclides.

Figure: 25 TAC §289.202(ggg)(4)(A)(iii)(V) [Figure: 25 TAC §289.202(ggg)(4)(A)(iii)(V)]

(iv) (No change.)

(v) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in clause (iii)(V) of this subparagraph and some of which are listed in clause (iv)(VI) of this subparagraph, classification shall be determined as follows. [;]

(I) - (II) (No change.)

(vi) - (viii) (No change.)

(B) - (C) (No change.)

(5) Time requirements for record keeping.

Figure: 25 TAC §289.202(ggg)(5) [Figure: 25 TAC §289.202(ggg)(5)]

(6) Acceptable surface contamination levels.

Figure: 25 TAC §289.202(ggg)(6) [Figure: 25 TAC §289.202(ggg)(6)]

(7) Concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility (for use in subsection (fff) of this section). The following table contains concentration and activity limits of nuclides for disposal in a Type I municipal solid waste site or a hazardous waste facility.

Figure: 25 TAC §289.202(ggg)(7) [Figure: 25 TAC §289.202(ggg)(7)]

(8) Cumulative occupational exposure form. [The following] RC Form 202-2, found in the attached graphic, Figure: 25 TAC §289.202(ggg)(8), or other equivalent clear and legible record[,] of all the information required on that form, must [is to] be used to document

cumulative occupational exposure history: [(Please find RC Form 202-2 at the end of this section.)]

Figure: 25 TAC §289.202(ggg)(8) (No change.)

(9) Occupational exposure form. [The following,] RC Form 202-3, found in the attached graphic, Figure: 25 TAC §289.202(ggg)(9), or other equivalent clear and legible record[,] of all the information required on that form, must [is to] be used to document occupational exposure record for a monitoring period: [(Please find RC Form 202-3 at the end of this section.)]

Figure: 25 TAC §289.202(ggg)(9) (No change.)

(hhh) (No change.)

Figure: 25 TAC §289.202(ggg)(2)(F) -

see separate file (289.202-b RAM2 PropGraphic...pdf)

Figure: 25 TAC §289.202(ggg)(4)(A)(iii)(V)

Concentration Radionuclide	curie/cubic meter *	nanocurie/gram **
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half life greater than 5 years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

* To convert the Ci/ m³ values to gigabecquerel (GBq) per cubic meter, multiply the Ci/ m³ value by 37.

** To convert the nCi/g values to Becquerel (Bq) per gram, multiply the nCi/g value by 37.

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(y)(5)	Utilization Records for Portable and Mobile Devices	3 years after the record is made
(ll)(4)	Records at Authorized Use/ Storage Sites	While site is authorized on license/registration
(mm)(1)(A)	Radiation Protection Programs	Until termination of license/registration
(mm)(1)(B)	Program Audits	3 years after the record is made
(nn)(1)	Routine Surveys, Instrument Calibrations and Package Monitoring	3 years after the record is made
(nn)(3)	Surveys; Measurements and/or Calculations Used for Dose Determination; Results of Air Sampling, Surveys and Bioassays; Measurements, Calculations Used to Determine Release of Radioactive Effluents	Until termination of license/registration
(oo)	Tests for leakage/ contamination of sealed sources	5 years after the record is made
(pp)	Lifetime Cumulative Occupational Radiation Dose, RC Form 202-2	Until termination of license
(pp)	Records Used to Prepare RC Form 202-2	3 years after the record is made

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(qq)	Planned Special Exposures	Until termination of license
(rr)(1) - (3)	Individual Monitoring Results; RC Form 202-3	Entries at no > 1 year intervals, by April 30 each year; Maintain until termination of license/registration
(rr)(5)	Records Used to Prepare RC Form 202-3	3 years after the record is made
(rr)(4)	Embryo/Fetus Dose	Until termination of license/registration
(ss)	Dose to Individual Members of the Public	Until termination of license/registration
(tt)	Discharge, Treatment, or Transfer for Disposal	Until termination of license/registration
(uu)	Entry Control Device Testing for Very High Radiation Areas	3 years after the record is made

NUCLIDE ^a	AVERAGE ^{b,c,f}	MAXIMUM ^{b,d,f}	REMOVABLE ^{b,c,f}
U-nat, U-235, U-238, and associated decay products except Ra-226, Th-230, Ac-227, and Pa-231	5,000 dpm alpha/ 100 cm ²	15,000 dpm alpha/ 100 cm ²	1,000 dpm alpha/ 100 cm ²
Transuranics, Ra-223, Ra-224, Ra-226, Ra-228, Th-nat, Th-228, Th-230, Th-232, U-232, Pa-231, Ac-227, Sr-90, I-129	1,000 dpm/100 cm ²	3,000 dpm/100 cm ²	200 dpm/100 cm ²
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above	5,000 dpm beta, gamma/100 cm ²	15,000 dpm beta, gamma/100 cm ²	1,000 dpm beta, gamma/100 cm ²
Tritium (applicable to surface and subsurface) ^g	NA	NA	10,000 dpm/100 cm ²

- ^a Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides shall apply independently.
- ^b As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- ^c Measurements of average contamination level should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each object.
- ^d The maximum contamination level applies to an area of not more than 100 cm².

- ^e The amount of removable radioactive material per 100 cm² of surface area shall be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels shall be reduced proportionally and the entire surface shall be wiped.
- ^f The radiation levels associated with surface contamination resulting from beta-gamma emitters shall not exceed 0.2 mrad/hr at 1 centimeter for an average and shall not exceed 1.0 mrad/hr at 1 centimeter as a maximum, as measured through not more than 7 mg/cm² of total absorber. The external gamma exposure rate shall not exceed 5 microentgen per hour above background at 1 meter from the surface, and for soil 10 microentgen per hour above background at 1 meter.
- ^g Property recently exposed or decontaminated, shall have measurements (smears) at regular time intervals to ensure that there is not a build-up of contamination over time. Because tritium typically penetrates material it contacts, the surface guidelines in group 4 are not applicable to tritium. The agency has reviewed the analysis conducted by the Department of Energy Tritium Surface Contamination Limits Committee ("Recommended Tritium Surface Contamination Release Guides," February 1991), and has assessed potential doses associated with the release of property containing residual tritium. The agency recommends the use of the stated guideline as an interim value for removable tritium. Measurements demonstrating compliance of the removable fraction of tritium on surfaces with this guideline are acceptable to ensure that non-removable fractions and residual tritium in mass will not cause exposures that exceed dose limits as specified in this section and agency constraints.

Nuclides	Concentrations Limit (Ci/m ³)	Annual Generator Disposal Limit (Ci/yr)
F-18	3×10^{-1}	8
Si-31	$1 \times 10^{+2}$	$3 \times 10^{+3}$
Na-24	9×10^{-4}	2×10^{-2}
P-32	2	$5 \times 10^{+1}$
P-33	10	$3 \times 10^{+2}$
S-35	9	$2 \times 10^{+2}$
Ar-41	3×10^{-1}	8
K-42	2×10^{-2}	5×10^{-1}
Ca-45	4	$1 \times 10^{+2}$
Ca-47	2×10^{-2}	5×10^{-1}
Sc-46	2×10^{-3}	5×10^{-2}
Cr-51	6×10^{-1}	$2 \times 10^{+1}$
Fe-59	5×10^{-3}	1×10^{-1}
Co-57	6×10^{-2}	2
Co-58	1×10^{-2}	3×10^{-1}
Zn-65	7×10^{-3}	2×10^{-1}
Ga-67	3×10^{-1}	8
Se-75	5×10^{-2}	1
Br-82	2×10^{-3}	5×10^{-2}
Rb-86	4×10^{-2}	1
Sr-85	2×10^{-2}	5×10^{-1}
Sr-89	8	$2 \times 10^{+2}$
Y-90	4	$1 \times 10^{+2}$
Y-91	4×10^{-1}	10
Zr-95	8×10^{-3}	2×10^{-1}
Nb-95	8×10^{-3}	2×10^{-1}
Mo-99	5×10^{-2}	1
Tc-99m	1	$3 \times 10^{+1}$
Rh-106	1	$3 \times 10^{+1}$
Ag-110m	2×10^{-3}	5×10^{-2}
Cd-115m	2×10^{-1}	5
In-111	9×10^{-2}	2

Nuclides	Concentrations Limit (Ci/m ³)	Annual Generator Disposal Limit (Ci/yr)
In-113m	9	$2 \times 10^{+2}$
Sn-113	6×10^{-2}	2
Sn-119	$2 \times 10^{+1}$	$5 \times 10^{+2}$
Sb-124	2×10^{-3}	5×10^{-2}
Te-129	2×10^{-1}	5
I-123	4×10^{-1}	$1 \times 10^{+1}$
I-125	7×10^{-1}	$2 \times 10^{+1}$
I-131	4×10^{-2}	1
I-133	2×10^{-2}	5×10^{-1}
Xe-127	8×10^{-2}	2
Xe-133	1	$3 \times 10^{+1}$
Ba-140	2×10^{-3}	5×10^{-2}
La-140	2×10^{-3}	5×10^{-2}
Ce-141	4×10^{-1}	$1 \times 10^{+1}$
Ce-144	1×10^{-3}	3×10^{-2}
Pr-143	6	$2 \times 10^{+2}$
Nd-147	7×10^{-2}	2
Yb-169	6×10^{-2}	2
Ir-192	1×10^{-2}	3×10^{-1}
Au-198	3×10^{-2}	8×10^{-1}
Hg-197	8×10^{-1}	$2 \times 10^{+1}$
Tl-201	4×10^{-1}	$1 \times 10^{+1}$
Hg-203	1×10^{-1}	3

NOTE: In any case where there is a mixture in waste of more than one radionuclide, the limiting values for purposes of this paragraph shall be determined as follows.

For each radionuclide in the mixture, calculate the ratio between the quantity present in the mixture and the limit established in this paragraph for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Examples: If radionuclides a, b, and c are present in concentrations C_a , C_b , and C_c , and if the applicable concentrations are CL_a , CL_b , and CL_c respectively, then the concentrations shall be limited so that the following relationship exists:

$$(C_a/CL_a) + (C_b/CL_b) + (C_c/CL_c) \leq 1$$

If the total curies for radionuclides a, b, and c are represented A_a , A_b , and A_c , and the annual curie limit for each radionuclide is AL_a , AL_b , and AL_c , then the generator is limited to the following:

$$(A_a/AL_a) + (A_b/AL_b) + (A_c/AL_c) \leq 1$$

§289.251. Exemptions, General Licenses, and General License Acknowledgements.

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

(d) Exemptions for source material.

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

(3) Any person is exempt from this section and §289.252 of this title to the extent [if] that such person receives, possesses, uses, or transfers:

(A) (No change.)

(B) source material contained in the following products:

(i) glazed ceramic [**ceramics, for example**] tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;

(ii) glassware containing not more than 2% [10%] by weight source material or, for glassware manufactured before August 27, 2013, 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

(iii) - (iv) (No change.)

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

(E) depleted uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

[(i) the counterweights are manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission (NRC) authorizing distribution by the licensee in accordance with Title 10, Code of Federal Regulations (CFR), Part 40;]

(i) [(ii)] each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM" (The requirements specified in this clause need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were [are] impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," **[as previously]** required at that time [by this chapter]);

(ii) [(iii)] each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED" (The requirements specified in this clause need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were [are] impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM" [as previously] required at that time [by this chapter]); and

(iii) [(iv)] the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other [,] covering[, or labeling];

(F) (No change.)

(G) thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium; [,] and that the exemption contained in this subparagraph shall not be deemed to authorize either:

(i) the shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(ii) the receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or in other optical instruments;

(H) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie (μCi) (185 becquerels (Bq)) of uranium; or

(I) (No change.)

(4) (No change.)

(5) No person may initially transfer for sale or distribution a product containing source material to persons exempt under subsection (d)(3) of this section, Title 10, CFR, §40.13(c), or equivalent regulations of an agreement state, unless authorized by a license issued under Title 10, CFR, §40.52, to initially transfer such products for sale or distribution.

(A) Persons initially distributing source material in products covered by the exemptions in subsection (d)(3) of this section before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the agency takes final action on a pending application for license or

license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(B) Persons authorized by the agency, the NRC, or any agreement state to manufacture, process, or produce these materials or products containing source material, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under Title 10, CFR, §40.52, for distribution only. These persons are exempt from the requirements of §289.202 (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.203 (relating to Notices, Instructions, and Reports to Workers; Inspections), and §289.252(e)(1) and (2) of this title.

(e) Exemptions for radioactive material other than source material.

(1) Exempt concentrations.

(A) (No change.)

(B) No person may introduce radioactive material into a product or material, including waste, knowing or having reason to believe that it will be transferred to persons exempt in accordance with subparagraph (A) of this paragraph or equivalent regulations of the NRC or [,] any agreement state, [or any licensing state,] except in accordance with a specific license issued under [in accordance with] §289.252(i) of this title [or the general license provided in §289.252(ee) of this title].

(C) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license, as specified in §289.252 of this title, if the manufacturer, processor, or producer transfers radioactive material contained in a product or material that does not exceed the concentrations specified in subsection (l)(1) of this section, and that has been introduced into the product or material by a licensee holding a specific license issued by the NRC **[, any agreement state, or any licensing state]** that expressly authorizes such introduction. The exemption specified in this subparagraph does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Exempt quantities.

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

(D) No person may, for purposes of commercial distribution, transfer radioactive material in quantities greater than the individual quantities set forth in subsection (l)(2) of this section, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this paragraph or equivalent regulations of the NRC or [,] any agreement state, [or any licensing state,] except in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.18 or by the agency in accordance with §289.252(j) of this title, which states that the radioactive material may be

transferred by the licensee to persons exempt in accordance with this paragraph or the equivalent regulations of the NRC or [,] any agreement state[, or any licensing state].

(E) The schedule of quantities set forth in subsection (1)(2) of this section applies only to radioactive materials distributed as exempt quantities under a specific license issued by the agency, **[another licensing state, or]** the NRC [commission], or any agreement state. Subsection (1)(2) of this section does not apply to radioactive materials that have decayed from quantities not originally exempt and does not make such material, or the sources or devices in which the material is contained exempt **[except]** from the licensing requirements in this section or §289.252 of this title.

(F) (No change.)

(3) Exempt items.

(A) Certain items containing radioactive material.

(i) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from this chapter if that person receives, possesses, uses, transfers, or acquires the following products:

(I) timepieces, hands, or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(-a-) (No change.)

(-b-) 5 mCi (185 MBq) of tritium per hand;

(-c-) 15 mCi (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);

(-d-) 100 μ Ci (3.7 MBq) of promethium-147 per watch or 200 μ Ci (7.4 MBq) of promethium-147 per any other timepiece;

(-e-) 20 μ Ci (0.74 MBq) of promethium-147 per watch hand or 40 μ Ci (1.48 MBq) of promethium-147 per other timepiece hand;

(-f-) 60 μ Ci (2.22 MBq) of promethium-147 per watch dial or 120 μ Ci (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(-g-) - (-h-) (No change.)

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

(IV) such devices authorized before October 23, 2012, for use under a general license issued under **[in accordance with]** this section or equivalent regulations of the NRC or any **[an]** agreement state and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC, **any agreement state, or any licensing state**];

[(V) lock illuminators containing not more than 15 mCi (555 MBq) of tritium or not more than 2 mCi (74 MBq) of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 mrad/hr at 1 cm from any surface when measured through 50 mg/cm² of absorber;]

(V) **[(VI)]** balances of precision containing not more than 1 mCi (37 MBq) of tritium per balance or not more than 0.5 mCi (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;

(VI) **[(VII)]** marine compasses containing not more than 750 mCi (27.75 MBq) of tritium gas and other marine navigational instruments containing not more than 250 mCi (9.25 GBq) of tritium gas manufactured before December 17, 2007;

(VII) **[(VIII)]** electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material and that the levels of radiation from each electron tube containing radioactive material do not exceed 1 mrad/hr at 1 cm from any surface when measured through 7 mg/cm² of absorber (For purposes of this clause, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube designed to control electrical currents):

(-a-) 150 mCi (5.55 GBq) of tritium per microwave receiver protector tube or 10 mCi (0.37 GBq) of tritium per any other electron tube;

(-b-) 1 μ Ci (0.037 MBq) of cobalt-60;

(-c-) 5 μ Ci (0.185 GBq) of nickel-63;

(-d-) 30 μ Ci (1.11 GBq) of krypton-85;

(-e-) 5 μ Ci (0.185 GBq) of cesium-137; or

(-f-) 30 μ Ci (1.11 GBq) of promethium-147;

(VIII) **[(IX)]** ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding:

(-a-) the applicable quantity set forth in subsection (l)(2) of this section or 0.05 μCi (1.85 kilobecquerels (kBq)) of americium-241; and

(-b-) each instrument contains no more than 10 exempt quantities. For purposes of this subclause, an instrument's source(s) shall contain either one type or different types of radionuclides and an individual exempt quantity shall be composed of fractional parts of one or more of the exempt quantities in accordance with subsection (l)(2) of this section, provided that the sum of such fractions shall not exceed unity.

~~(IX)~~ **[(X)]** ionization chamber smoke detectors containing not more than 1 μCi (37 kBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(ii) (No change.)

(iii) Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in clause (i) of this subparagraph **[subparagraph]**, or who desires to initially transfer for sale or distribution such products containing radioactive material, shall apply for a specific license issued by the NRC in accordance with Title 10, CFR, §32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to clause (i) of this subparagraph.

(B) (No change.)

(C) Gas and aerosol detectors containing radioactive material.

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

(iii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by any **[an]** agreement state **[or a licensing state]** shall be considered exempt in accordance with clause (i) of this subparagraph, provided that the devices are labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of §289.252 of this title.

(D) (No change.)

(4) Exemption for capsules containing carbon-14 urea for "in vivo" diagnostic use in humans.

(A) Except as provided in subparagraphs (B) and (C) of this paragraph, a person is exempt from the requirements of this section and §289.256 of this title provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 1 μCi (37 kBq **[kilobecquerels]**) or less of carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use in humans.

(B) - (D) (No change.)

(f) General licenses. In addition to the requirements of this section, all general licenses, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202(ww) and (xx) of this title **[(relating to Standards for Protection Against Radiation from Radioactive Materials)]**, §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(1) Compliance history. In making a determination whether to revoke, suspend, or restrict a general license, the agency may consider the technical competence and compliance history of a general licensee. After an opportunity for a hearing, the agency may revoke, suspend, or restrict a general license if the general licensee's compliance history reveals that at least 3 [three] agency actions have been issued against the general licensee, within the previous 6 [six] years, that assess administrative or civil penalties against the general licensee, or that revoke or suspend the general license.

(2) (No change.)

(3) General licenses for source material.

(A) General license for small quantities of source material.

(i) [(A)] A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and federal, state and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, [not more than 15 pounds of source material at any one time] for research, development, educational, commercial, or operational purposes in the following forms and quantities: [.]

(I) no more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time.

(-a-) Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form.

(-b-) A person authorized to possess, use, and transfer source material as specified in this clause may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any 1 calendar year.

(-c-) Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium

and thorium at any one time until the NRC takes final action on any pending application submitted on or before August 27, 2014, for a specific license for such material; and may receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until the NRC takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

(II) no more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time.

(-a-) A person authorized to possess, use, and transfer source material as specified in this clause may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any 1 calendar year.

(-b-) A person may not alter the chemical or physical form of the source material possessed as specified in this clause unless it is accounted for in accordance with the limits of clause (i)(I) of this subparagraph; or

(III) no more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this clause; or

(IV) no more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material as specified in this clause may not receive more than a total of 70 kg (154 lb) of source material in any 1 calendar year.

[(i) A person authorized to use or transfer source material, in accordance with this general license, may not possess more than a total of 150 pounds of source material in any one calendar year.]

[(ii) Any person who receives, possesses, uses, or transfers [Persons who receive, possess, use, or transfer] source material in accordance with the general license in clause (i) of this subparagraph: [subparagraph (A) of this paragraph]

[(I) is [are] prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings [humans] except as may be authorized by the agency in a specific license; [,]

[(II) shall not abandon such source material. Source material may be disposed of as follows:

[(a-) a cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material in accordance with the general license to persons receiving the material for permanent disposal. The recipient of source

material transferred in accordance with this item is exempt from the requirements to obtain a license as specified in subsection (f)(3) of this section to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under §289.252 of this title; or

(-b-) in accordance with §289.202(ff) of this title:

(III) is subject to the regulations in subsection (f)(2), (h)(2), and (i) of this section and §§289.201(a), (b), (d) - (f), (i), (k), and (l); 289.202 (vv), (xx)(6) - (8) and (vv); 289.203(g)(3); 289.252(a), (w)(2), (x)(1) - (4), and (cc); and 289.257(b)(1) of this title; and

(IV) shall not export such source material except in accordance with Title 10, CFR, Part 110.

(iii) Any person who receives, possesses, uses, or transfers source material in accordance with clause (i) of this subparagraph shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used in accordance with this general license is not likely to result in exposures that exceed the limits in §289.202(ddd)(2) of this title.

(iv) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in (i) of this subparagraph is exempt from the regulations in §§289.202, 289.203 and 289.205 of this title to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the regulations of §289.202(ff) and (ddd)(2)(A) of this title to the extent necessary to meet the requirements of clauses (ii)(II) and (iii) of this subparagraph. However, this exemption does not apply to any person who also holds a specific license issued under §289.252 of this title.

(v) No person may initially transfer or distribute source material to persons generally licensed as specified in clause (i)(I) or (II) of this subparagraph, or equivalent regulations of any agreement state, unless authorized by a specific license issued in accordance with §289.252(cc)(6)(A) of this title or equivalent regulations of the NRC or any agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by clause (i) of this subparagraph may be continued until the NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

(B) - (C) (No change.)

(D) A general license is issued to receive, acquire, possess, use, or transfer depleted uranium contained in products or devices for the purpose of providing shielding, including beam shaping and collimation, in accordance with **[the provisions of]** clauses (i) - (iv) of this subparagraph.

(i) - (iv) (No change.)

(v) Any person receiving, acquiring, possessing, using, or transferring depleted uranium in accordance with the general license in this paragraph is exempt from the requirements of §289.202 of this title and §289.203 of this title **[(relating to Notices, Instructions, and Reports to Workers; Inspections)]** with respect to the depleted uranium covered by that general license.

(4) General licenses for radioactive material other than source material.

(A) General licenses for static elimination devices and ion generating tubes. A general license is issued to transfer, receive, acquire, possess, and use radioactive material incorporated in the devices or equipment specified in the following clauses (i) and (ii) of this paragraph that have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the NRC. In addition to the provisions of subsection (f) of this section, this general license is subject to the provisions of subsection (e)(1)(B) of this section and §289.252(cc) of this title:

(i) static elimination devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material totaling not more than 500 μCi (18.5 MBq) of polonium-210 per device; or

(ii) ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material totaling not more than 500 μCi (18.5 MBq) of polonium-210 per device or a total of not more than 50 mCi (1.85 GBq) of tritium per device.

(B) General license for luminous safety devices for aircraft.

(i) A general license is issued to receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(I) each device contains not more than 10 curies (Ci) (370 GBq) of tritium or 300 mCi (11.1 GBq) of promethium-147; and

(II) (No change.)

(ii) - (iii) (No change.)

(C) (No change.)

(D) General license for calibration, stabilization, and reference sources.

(i) (No change.)

(ii) The general license in clause (i) of this subparagraph applies only to calibration, stabilization, or reference sources that have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the NRC in accordance with Title 10, CFR, §32.57 or Title 10, CFR, §70.39 or that have been manufactured or initially transferred in accordance with the authorizations contained in a specific license issued to the manufacturer by the agency or [,] any agreement state, **[or any licensing state,]** in accordance with licensing requirements equivalent to those contained in Title 10, CFR, §32.57 or Title 10, CFR, §70.39.

(iii) Persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources in accordance with these general licenses:

(I) shall not possess at any one time, at any one location of storage or use, more than 5 μCi (185 kBq) each of americium-241, plutonium-238, plutonium-239, and radium-226 in such sources;

(II) shall not receive, possess, use, or transfer such source unless the source or the storage container bears a label that includes the following statements, or a substantially similar statement that contains the information in the following statements:

(-a-) (No change.)

(-b-) option 2, as appropriate:

Figure: 25 TAC §289.251(f)(4)(D)(iii)(II)(-b-)

[Figure: 25 TAC §289.251(f)(4)(D)(iii)(II)(-b-)]

(III) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a specific license from the agency, the NRC, or any **[an] agreement state], or a licensing state]** to receive the source;

(IV) - (V) (No change.)

(iv) (No change.)

(E) General license for ice detection devices.

(i) A general license is issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 μCi (1.85 MBq) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the NRC or each device has been manufactured in accordance with the authorizations contained in a specific license issued

by the agency or any agreement state to the manufacturer of such device in accordance with licensing requirements equivalent to those in Title 10, CFR, §32.61.

(ii) - (iii) (No change.)

(F) General license for intrastate transportation of radioactive material.

(i) A general license is issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident to transport, provided the transportation and storage is in accordance with the applicable requirements of §289.257 of this title insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those requirements shall be filed with the agency and the United States Department of Transportation (DOT). Persons who transport and store radioactive material in accordance with the general license in this paragraph are exempt from the requirements of §289.202 and §289.203 of this title except for §289.202(wv) - (yy) of this title.

(ii) A general license is issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those requirements shall be filed with the DOT, and with the agency in accordance with §289.202(wv) - (yy) of this title [and the DOT].

(G) General license for the use of radioactive material for certain *in vitro* clinical or laboratory testing, not to include research and development. (The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)

(i) A general license is issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with **[the provisions of]** clauses (ii) - (iii) of this subparagraph, the following radioactive materials in prepackaged units:

(I) iodine-125, in units not exceeding 10 μCi (0.37 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(II) iodine-131, in units not exceeding 10 μCi (0.37 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(III) carbon-14, in units not exceeding 10 μCi (0.37 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(IV) hydrogen-3 (tritium), in units not exceeding 50 μCi (1.85 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(V) iron-59, in units not exceeding 20 μCi (0.74 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(VI) selenium-75, in units not to exceed 10 μCi (0.37 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals;

(VII) mock iodine-125 reference or calibration sources, in units not exceeding 0.05 μCi (1850 Bq) of iodine-129 and 0.005 μCi of americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals; or

(VIII) cobalt-57, in units not exceeding 10 μCi (0.37 MBq) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals.

(ii) A person who receives, acquires, possesses, or uses radioactive material in accordance with the general license in clause (i) of this subparagraph shall comply with the following.

(I) The general licensee shall not possess at any one time, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 μCi (7.4 MBq).

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

(IV) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it in accordance with a specific license issued by the agency, the NRC, or any agreement state, **[or any licensing state,]** nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(V) (No change.)

(iii) The general licensee shall not receive, acquire, possess, or use radioactive material in accordance with the general license in clause (i) of this subparagraph:

(I) except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued in accordance with §289.252(p) of this title or in accordance with the requirements **[provisions]** of a specific license issued by the NRC or **[,]** any agreement state**[, or any licensing state]** that authorizes the

manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to general licensees in accordance with this subparagraph or its equivalent; and

(II) unless one of the statements in the following figures, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

(-a-) (No change.)

(-b-) option 2, as appropriate:

Figure: 25 TAC §289.251(f)(4)(G)(iii)(II)(-b-)

[Figure: 25 TAC §289.251(f)(4)(G)(iii)(II)(-b-)]

(iv) (No change.)

(H) General license for certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.

(i) (No change.)

(ii) The general license in clause (i) of this subparagraph applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the agency in accordance with §289.252(l) of this title or in a specific license issued by the NRC or any [, **an**] agreement state[, **or a licensing state**] that authorizes distribution of devices to persons generally licensed by the NRC or any [, **an**] agreement state[, **or a licensing state**].

(iii) (No change.)

(iv) Any person who receives, acquires, possesses, uses, or transfers radioactive material in a device in accordance with the general license in this subparagraph shall do the following:

(I) (No change.)

(II) assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month [**six-month**] intervals or at such other intervals as specified in the label; however:

(-a-) (No change.)

(-b-) devices containing only tritium or not more than 100 μCi (3.7 MBq) of other beta and/or gamma emitting material or 10 μCi (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose, provided that each source is tested for leakage within 6 [six] months prior to being used or transferred;

(III) assure that the tests required by subclause (II) of this clause and other testing, installation (removal of the manufacturer's lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, its shielding or containment, are performed:

(-a) - (-b) (No change.)

(-c) by a person holding a specific license from the agency, the NRC, or any [an] agreement state, **or a licensing state** to perform such activities;

(IV) maintain records for inspection by the agency documenting [showing] compliance with the requirements of subclauses (II) and (III) of this clause. The records shall include [show] the test results. The records also shall identify the device tested by manufacturer, model and serial number of the device, serial number of the sealed source, and show the dates of performance of and the names of persons performing testing, installation, servicing, and removal from location of installation, of the radioactive material, its shielding or containment. Retention shall be as follows:

(-a-) records for tests for leakage of radioactive material required by subclause (II) of this clause shall be kept for 3 [three] years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(-b-) records of the test of the on-off mechanism and indicator required by subclause (II) of this clause shall be kept for 3 [three] years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of; and

(-c-) records of the testing, installation (removal of the manufacturer's lock and initial alignment of the radiation beam), servicing, and removal from location of installation involving the radioactive materials, its shielding or containment required by subclause (III) of this clause shall be kept for 3 [three] years from the date of the recorded event or until the device is transferred or disposed of;

(V) - (VI) (No change.)

(VII) immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism, or indicator, or upon the detection of 185 Bq [becquerels] (0.005 μCi) or more of removable radioactive material. The device shall not be operated until it has been repaired by the manufacturer or other person holding a specific license

from the agency, the NRC, or any [an] agreement state, **or a licensing state**] to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device. A report, prepared in accordance with §289.202(xx) and (yy) of this title, containing a brief description of the event and the remedial action taken and in the case of detection of 185 Bq [becquerels] (0.005 μ Ci) or more removable radioactive material or failure of, or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use shall be furnished to the agency within 30 days. Under these circumstances, the requirements in §289.202(ddd) of this title may be applicable, as determined by the agency on a case-by-case basis;

(VIII) (No change.)

(IX) transfer or dispose of the device containing radioactive material only by export in accordance with Title 10, CFR, Part 110, by transfer to another general licensee as authorized in subclauses (XII) and (XVI) of this clause or to a person authorized to receive the device by a specific license issued by the agency in accordance with §289.252(l) of this title, or an equivalent specific license issued by the NRC or any [, an] agreement state, **[or a licensing state]**, or as otherwise approved under subclause (XI) of this clause;

(X) furnish a report to the agency within 30 days after the transfer or export of a device to a specific licensee. The report must contain the following:

(-a) - (-b) (No change.)

(-c) date of the transfer; [.]

(XI) obtain written agency approval before transferring the device to any other specific licensee not specifically identified in subclause (IX) of this clause; however, a holder of a specific license may transfer a device for possession and use in accordance with [under] its own specific license without prior approval, if, the holder:

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

(-d) reports the transfer as specified in [under] subclause (X) of this clause; [.]

(XII) transfer the device to another general licensee only if:

(-a) (No change.)

(-b) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee; [.]

(XIII) - (XIV) (No change.)

(XV) not hold devices that are not in use for longer than 24 months following the last principal activity use [two years].

~~(-a-)~~ If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by clause (iv) of this subparagraph need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use.

~~(-b-)~~ Devices kept in standby for future use are excluded from the 24-month [two-year] time limit if the agency approves a plan for future use submitted by the licensee. Licensees shall submit plans at least 30 days prior to the end of the 24 months of nonuse.

~~(-c-)~~ The general licensee shall perform [performs] quarterly physical inventories of these devices while they are in standby. The licensee shall make, **[and]** maintain, and retain for intervals of 5 [five] years, records of the quarterly physical inventories for inspection by the agency;

(XVI) - (XIX) (No change.)

(I) - (J) (No change.)

(K) General license for certain items and self-luminous products containing radium-226.

(i) (No change.)

(ii) Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with this subparagraph shall do the following.

(I) - (IV) (No change.)

(V) Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under [in accordance with] this section, or under equivalent regulations of the NRC, or any agreement state.

(VI) Respond to written requests from the agency, the NRC, or any agreement state to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general

licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency, the NRC, or any agreement state **[agency's Radiation Safety Licensing Branch]** a written justification for the request.

(g) - (k) (No change.)

(l) Appendices.

(1) Exempt concentrations.

Figure: 25 TAC §289.251(l)(1) **[Figure: 25 TAC §289.251(l)(1)]**

(2) Exempt quantities.

Figure: 25 TAC §289.251(l)(2) **[Figure: 25 TAC §289.251(l)(2)]**

Figure: 25 TAC §289.251(f)(4)(D)(iii)(II)(-b-)

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the agency or equivalent regulations of the NRC or any agreement state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of Manufacturer or Initial Transferor

Figure: 25 TAC §289.251(f)(4)(G)(iii)(II)(-b-)

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

Name of Manufacturer

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	1×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-138	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** $\mu\text{Ci/gm}$ for solids

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 ($T/2=9.2$ h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** $\mu\text{Ci/gm}$ for solids

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}

* Values are given in Column I only for those materials normally used in gases.

** $\mu\text{Ci/gm}$ for solids

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-4}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}

* Values are given in Column I only for those materials normally used in gases.

** $\mu\text{Ci/gm}$ for solids

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration $\mu\text{Ci/ml}^*$	Liquid and Solid Concentration $\mu\text{Ci/ml}^{**}$
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}

* Values are given in Column I only for those materials normally used in gases.

** $\mu\text{Ci/gm}$ for solids

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration μCi/ml*	Liquid and Solid Concentration μCi/ml**
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		1×10^{-10}	1×10^{-6}

NOTE 1: Many radioisotopes disintegrate into isotopes that are also radioactive. In expressing the concentrations in this paragraph, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of subsection (d) of this section where a combination of isotopes is involved, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in this paragraph for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (for example, unity).

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt Concentration of Isotope A}} +$$

$$\frac{\text{Concentration of Isotope B in Product}}{\text{Exempt Concentration of Isotope B}} \leq 1$$

* Values are given in Column I only for those materials normally used in gases.

** μCi/gm for solids

<u>Radioactive Material</u>	<u>Microcuries</u>
Antimony-122 (Sb-122)	100
Antimony-124 (Sb-124)	10
Antimony-125 (Sb-125)	10
Arsenic-73 (As-73)	100
Arsenic-74 (As-74)	10
Arsenic-76 (As-76)	10
Arsenic-77 (As-77)	100
Barium-131 (Ba-131)	10
Barium-133 (Ba-133)	10
Barium-140 (Ba-140)	10
Bismuth-210 (Bi-210)	1
Bromine-82 (Br-82)	10
Cadmium-109 (Cd-109)	10
Cadmium-115m (Cd-115m)	10
Cadmium-115 (Cd-115)	100
Calcium-45 (Ca-45)	10
Calcium-47 (Ca-47)	10
Carbon-14 (C-14)	100
Cerium-141 (Ce-141)	100
Cerium-143 (Ce-143)	100
Cerium-144 (Ce-144)	1
Cesium-129 (Cs-129)	100
Cesium-131 (Cs-131)	1,000
Cesium-134m (Cs-134m)	100
Cesium-134 (Cs-134)	1
Cesium-135 (Cs-135)	10
Cesium-136 (Cs-136)	10
Cesium-137 (Cs-137)	10
Chlorine-36 (Cl-36)	10
Chlorine-38 (Cl-38)	10
Chromium-51 (Cr-51)	1,000
Cobalt-57 (Co-57)	100
Cobalt-58m (Co-58m)	10
Cobalt-58 (Co-58)	10
Cobalt-60 (Co-60)	1
Copper-64 (Cu-64)	100
Dysprosium-165 (Dy-165)	10
Dysprosium-166 (Dy-166)	100

<u>Radioactive Material</u>	<u>Microcuries</u>
Erbium-169 (Er-169)	100
Erbium-171 (Er-171)	100
Europium-152 (Eu-152) 9.2h	100
Europium-152 (Eu-152) 13 yr	1
Europium-154 (Eu-154)	1
Europium-155 (Eu-155)	10
Fluorine-18 (F-18)	1,000
Gadolinium-153 (Gd-153)	10
Gadolinium-159 (Gd-159)	100
Gallium-67 (Ga-67)	100
Gallium-72 (Ga-72)	10
Germanium-68 (Ge-68)	10
Germanium-71 (Ge-71)	100
Gold-195 (Au-195)	10
Gold-198 (Au-198)	100
Gold-199 (Au-199)	100
Hafnium-181 (Hf-181)	10
Holmium-166 (Ho-166)	100
Hydrogen-3 (H-3)	1,000
Indium-111 (In-111)	100
Indium-113m (In-113m)	100
Indium-114m (In-114m)	10
Indium-115m (In-115m)	100
Indium-115 (In-115)	10
Iodine-123 (I-123)	100
Iodine-125 (I-125)	1
Iodine-126 (I-126)	1
Iodine-129 (I-129)	0.1
Iodine-131 (I-131)	1
Iodine-132 (I-132)	10
Iodine-133 (I-133)	1
Iodine-134 (I-134)	10
Iodine-135 (I-135)	10
Iridium-192 (Ir-192)	10
Iridium-194 (Ir-194)	100
Iron-52 (Fe-52)	10
Iron-55 (Fe-55)	100
Iron-59 (Fe-59)	10
Krypton-85 (Kr-85)	100

<u>Radioactive Material</u>	<u>Microcuries</u>
Krypton-87 (Kr-87)	10
Lanthanum-140 (La-140)	10
Lutetium-177 (Lu-177)	100
Manganese-52 (Mn-52)	10
Manganese-54 (Mn-54)	10
Manganese-56 (Mn-56)	10
Mercury-197m (Hg-197m)	100
Mercury-197 (Hg-197)	100
Mercury-203 (Hg-203)	10
Molybdenum-99 (Mo-99)	100
Neodymium-147 (Nd-147)	100
Neodymium-149 (Nd-149)	100
Nickel-59 (Ni-59)	100
Nickel-63 (Ni-63)	10
Nickel-65 (Ni-65)	100
Niobium-93m (Nb-93m)	10
Niobium-95 (Nb-95)	10
Niobium-97 (Nb-97)	10
Osmium-185 (Os-185)	10
Osmium-191m (Os-191m)	100
Osmium-191 (Os-191)	100
Osmium-193 (Os-193)	100
Palladium-103 (Pd-103)	100
Palladium-109 (Pd-109)	100
Phosphorus-32 (P-32)	10
Platinum-191 (Pt-191)	100
Platinum-193m (Pt-193m)	100
Platinum-193 (Pt-193)	100
Platinum-197m (Pt-197m)	100
Platinum-197 (Pt-197)	100
Polonium-210 (Po-210)	0.1
Potassium-42 (K-42)	10
Potassium-43 (K-43)	10
Praseodymium-142 (Pr-142)	100
Praseodymium-143 (Pr-143)	100
Promethium-147 (Pm-147)	10
Promethium-149 (Pm-149)	10
Rhenium-186 (Re-186)	100
Rhenium-188 (Re-188)	100

<u>Radioactive Material</u>	<u>Microcuries</u>
Rhodium-103m (Rh-103m)	100
Rhodium-105 (Rh-105)	100
Rubidium-81 (Rb-81)	10
Rubidium-86 (Rb-86)	10
Rubidium-87 (Rb-87)	10
Ruthenium-97 (Ru-97)	100
Ruthenium-103 (Ru-103)	10
Ruthenium-105 (Ru-105)	10
Ruthenium-106 (Ru-106)	1
Samarium-151 (Sm-151)	10
Samarium-153 (Sm-153)	100
Scandium-46 (Sc-46)	10
Scandium-47 (Sc-47)	100
Scandium-48 (Sc-48)	10
Selenium-75 (Se-75)	10
Silicon-31 (Si-31)	100
Silver-105 (Ag-105)	10
Silver-110m (Ag-110m)	1
Silver-111 (Ag-111)	100
Sodium-22 (Na-22)	10
Sodium-24 (Na-24)	10
Strontium-85 (Sr-85)	10
Strontium-89 (Sr-89)	1
Strontium-90 (Sr-90)	0.1
Strontium-91 (Sr-91)	10
Strontium-92 (Sr-92)	10
Sulphur-35 (S-35)	100
Tantalum-182 (Ta-182)	10
Technetium-96 (Tc-96)	10
Technetium-97m (Tc-97m)	100
Technetium-97 (Tc-97)	100
Technetium-99m (Tc-99m)	100
Technetium-99 (Tc-99)	10
Tellurium-125m (Te-125m)	10
Tellurium-127m (Te-127m)	10
Tellurium-127 (Te-127)	100
Tellurium-129m (Te-129m)	10
Tellurium-129 (Te-129)	100
Tellurium-131m (Te-131m)	10

<u>Radioactive Material</u>	<u>Microcuries</u>
Tellurium-132 (Te-132)	10
Terbium-160 (Tb-160)	10
Thallium-200 (Tl-200)	100
Thallium-201 (Tl-201)	100
Thallium-202 (Tl-202)	100
Thallium-204 (Tl-204)	10
Thulium-170 (Tm-170)	10
Thulium-171 (Tm-171)	10
Tin-113 (Sn-113)	10
Tin-125 (Sn-125)	10
Tungsten-181 (W-181)	10
Tungsten-185 (W-185)	10
Tungsten-187 (W-187)	100
Vanadium-48 (V-48)	10
Xenon-131m (Xe-131m)	1,000
Xenon-133 (Xe-133)	100
Xenon-135 (Xe-135)	100
Ytterbium-175 (Yb-175)	100
Yttrium-87 (Y-87)	10
Yttrium-88 (Y-88)	10
Yttrium-90 (Y-90)	10
Yttrium-91 (Y-91)	10
Yttrium-92 (Y-92)	100
Yttrium-93 (Y-93)	100
Zinc-65 (Zn-65)	10
Zinc-69m (Zn-69m)	100
Zinc-69 (Zn-69)	1,000
Zirconium-93 (Zr-93)	10
Zirconium-95 (Zr-95)	10
Zirconium-97 (Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

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

(A) The first period is the time from receipt of an application by the agency [Division of Licensing, Registration and Standards] to the date of issuance or denial of the license or a written notice outlining why the application is incomplete or unacceptable. This time period is 60 days.

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

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

(11) - (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 6 [six] months and make, [and] maintain, and retain records of the inventory of the radioactive sealed sources authorized for use on the license every 6 [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) a bachelor's degree in health physics, radiological health, physical science or a biological science with a physical science minor and 4 **[four]** years of applied health physics experience in a program with radiation safety issues similar to those in the program to be managed;

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

(C) 2 **[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 **[Nuclear]** 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) Duties and responsibilities of the Radiation Safety Committee (RSC). The duties and responsibilities of the RSC **[Radiation Safety Committee (RSC)]** include but are not limited to the following:

(1) meeting as often as necessary to conduct business but no less than 3 **[three]** times a year;

(2) - (11) (No change.)

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

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

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

(C) establishment of an RSC, including names and qualifications, with duties and responsibilities in accordance with subsection (g) of this section. The RSC shall be composed of an RSO, a representative of executive management, and 1 **[one]** or more persons trained or experienced in the safe use of radioactive materials.

(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 **[is]** 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.
[; and]

(2) The **[the]** applicant shall provide **[provides]** reasonable assurance that:

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

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

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

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

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

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

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

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

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

(I) (No change.)

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

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

(III) (No change.)

(D) - (F) (No change.)

(2) In the event the applicant desires that the device be required to be tested at intervals longer than 6 [six] months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material, or for both, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar devices and by design features that have a significant bearing on the probability or consequences of radioactive material leakage from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for radioactive material leakage, the agency will consider information that includes, but is not limited to the following:

(A) - (J) (No change.)

(3) In the event the applicant desires that the general licensee in accordance with §289.251(f)(4)(H) of this title or in accordance with equivalent regulations of the NRC or any [, **an**] agreement state, [**or a licensing state**,] be authorized to mount the device, collect the sample to be analyzed by a specific licensee for radioactive material leakage, perform maintenance of the device consisting of replacement of labels, rust and corrosion prevention, and for fixed

gauges, repair and maintenance of sealed source holder mounting brackets, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices in accordance with the general license, is unlikely to cause that individual to receive an annual dose in excess of 10% of the limits specified in §289.202(f) of this title.

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

(A) (No change.)

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

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

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

(G) (No change.)

(5) - (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 agency or any [**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) (No change.)

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

(iv) (No change.)

(D) make, maintain, and retain records required by this paragraph for inspection by the agency in accordance with subsection (mm) of this section **[keep records for three years following the date of the recorded event]**, including **[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 or any **[, an]** agreement state**[, or a licensing state]**.

(i) The records shall include **[show]** the following:

(I) the date of each commercial distribution;

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

(ii) (No change.)

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

(9) (No change.)

(m) (No change.)

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

(1) (No change.)

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

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

(1) (No change.)

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

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

(4) - (5) (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 [**megabecquerel**]) each;

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

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

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

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

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

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

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

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

(B) (No change.)

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

(A) (No change.)

(B) option 2:

Figure: 25 TAC §289.252(p)(3)(B) [Figure: 25 TAC §289.252(p)(3)(B)]

(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;"

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

(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, maintain, and retain records of the tests and checks required in this paragraph **[for a minimum of three years]** 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 **[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 **[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 **[for a period of three years]**.

(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, maintain, and retain [keep] records including [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 any [of an] agreement state. The records shall be maintained for inspection by the agency in accordance with subsection (mm) of this section [for a period of two years for inspection by the agency] and shall include [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 specified 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) (No change.)

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

(i) the intended recipients are licensed in accordance with this section or equivalent regulations of the NRC or any [, an] agreement state[, or a licensing state]; or

(ii) - (iii) (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 2 [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 2 [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, maintain, and retain a record of the results of each test **[and retain each record for 3 years after the record is made]** for inspection by the agency in accordance with subsection (mm) of this section.

(11) Licensees shall not hold radioactive waste, sources, or devices not authorized for disposal by decay in storage, and that are not in use for longer than 24 months following the last principal activity use. Sources and devices kept in standby for future use may be excluded from the 24-month time limit if the agency approves a plan for future use. A plan for an alternative disposal timeframe may be submitted by the licensee if the 24-month time limit cannot be met. Licensees shall submit plans to the agency 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 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 as specified in [under] the license have been conducted for a period of 24 months; or

(D) (No change.)

(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.

(16) - (17) (No change.)

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

(cc) Transfer of material.

(1) (No change.)

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

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

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

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

(E) (No change.)

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

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

(A) (No change.)

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

(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 in accordance with §289.251(f)(3) of this title; Title 10, CFR, §40.22; or equivalent regulations of any agreement state, will be approved if:

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

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

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

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

(iv) report transfers as follows:

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

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

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

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

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

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

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

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

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

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

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

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

(v) maintain all information that supports the reports required by this subparagraph concerning each transfer to a general licensee for inspection by the agency in accordance with subsection (mm) of this section.

(dd) (No change.)

(ee) Reciprocal recognition of licenses.

(1) Subject to this section, any person who holds a specific license from the NRC or [,] 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) - (D) (No change.)

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

(i) specifically licensed by the agency, the NRC, or any **[another] agreement state[, or another licensing state]** to receive such material, or

(ii) (No change.)

(F) the **[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 the NRC or any **[, 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 **[state]** of Texas. Each report shall identify by name and address, each general licensee to whom the device is transferred, the type of device transferred by manufacturer's name, model and serial number of the device, and serial number of the sealed source, and the quantity and type of radioactive material contained in the device;

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

(C) - (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, maintain, and retain [keep] records of information important to the safe and effective decommissioning of the facility in an identified location for inspection by the agency in accordance with §289.252(mm) of this section [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 paragraphs (2) - (23) of this subsection, except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kilograms (4,409 pounds) is not exempt from the requirements of this subsection. The licensee shall implement the following requirements to secure the radioactive waste:

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

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

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

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

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

(A) General.

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

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

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

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

(C) Applicability.

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

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

(II) reviewing officials.

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

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

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

(3) Access authorization program requirements.

(A) Granting unescorted access authorization.

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

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

(B) Reviewing officials.

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

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

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

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

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

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

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

(C) Informed consent.

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

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

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

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

(G) Right to correct and complete information.

(i) 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 must 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 agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

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

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

and (ii) a copy of the current access authorization program procedures;
authorization. (iii) the current list of persons approved for unescorted access

(4) Background investigations.

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

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

(ii) verification of true identity. Licensees shall:

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

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

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

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

(V) maintain the certification and all related documents for inspection by the 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 as specified in paragraphs (2) and (3), this paragraph, and paragraphs (5) - (8) of this subsection must be limited to whether the individual has been and continues to be trustworthy and reliable;

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

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

(B) Grandfathering.

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

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

(C) Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification

and criminal history records check in accordance with paragraph (5) of this subsection. The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

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

(A) General performance objective and requirements.

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

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

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

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

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

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

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

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

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

history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the requirements of paragraph (7)(C) of this subsection.

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

(B) Prohibitions.

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

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

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

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

(C) Procedures for processing of fingerprint checks.

(i) For the purpose of complying with paragraphs (2) - (4), this paragraph, and paragraphs (6) - (8) of this subsection, licensees shall use an appropriate method listed in Title 10, CFR, §37.7, to submit to the U.S. Nuclear Regulatory Commission, Director, Division of 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 (630) 829-9565, 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) 492-3531.) 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 as specified in §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 1 and category 2 quantities of radioactive material;

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

(xii) any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the federal agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall maintain this documentation for inspection by the 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 must be provided to the licensee. The licensee shall maintain and 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 must be provided to the licensee. The licensee shall maintain 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, or paragraph (8) of this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

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

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

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

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

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

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

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

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

(C) Review records must be maintained for inspection by the 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 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 must include the program features, as appropriate, described in paragraphs (10) - (16) of this subsection.

(10) General security program requirements.

(A) Security plan.

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

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

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

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

(iii) A licensee shall revise its security plan as necessary to ensure the effective implementation of 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 maintain 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 maintain 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 must be approved in writing by the individual with overall responsibility for the security program.

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

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

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

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

(IV) the appropriate response to security alarms.

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

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

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

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

(III) relevant results of inspections by the agency; 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) 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 must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in paragraph (4)(A)(ii) - (vii) of this subsection.

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

(I) the categories of individuals listed in paragraph (6)(A)(i) 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, maintain, and retain as a record for inspection by the agency in accordance with subsection (mm) of this section:

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

(II) the list of individuals approved for access to the security plan 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 must include:

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

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

(B) The licensee shall notify the 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 must 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 must, at a minimum, allow unescorted access only to approved individuals through:

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

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

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

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

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

(13) Monitoring, detection and assessment.

(A) Monitoring and detection.

(i) Licensees shall:

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

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

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

(ii) Monitoring and detection must be performed by:

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

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

(III) a monitored video surveillance system;

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

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

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

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

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

(-b-) continuous monitored video surveillance; or

(-c-) direct visual surveillance; and

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

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

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

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

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

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

(14) Maintenance and testing.

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

(B) The licensee shall maintain records on the maintenance and testing activities for inspection by the 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

(16) Security program review.

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

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

(i) Each review report must:

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

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

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

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

(C) The licensee shall make, maintain, and retain the documentation of the review required under subparagraph (B) of this paragraph for inspection by the 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) Each initial telephonic notification required by subparagraphs (A) and (B) of this paragraph must be followed within a period of 30 days by a written report submitted to the agency. The report must 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, or any agreement state shall meet the license verification requirements listed below instead of those listed in subsection (cc)(4) of this section.

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the agency, the NRC, or any agreement 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, or any agreement 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 must include:

(I) the license number;

(II) the current revision number;

(III) the issuing authority;

(IV) the expiration date; and

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

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

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

(D) The transferor shall keep a copy of the verification documentation required under this paragraph as a record for inspection by the 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 pursuant to subparagraph (B) of this paragraph, shall promptly notify the receiving licensee of the new no-later-than arrival time.

(E) The licensee shall make, maintain, and retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for inspection by the 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 must 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 Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(II) Notifications to the NRC must 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 must 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 must 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 must 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 must contain the following information, if available at the time of notification:

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

(ii) the license numbers of the shipper and receiver;

(iii) a description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(iv) the point of origin of the shipment and the estimated time and date that shipment will commence;

(v) the estimated time and date that the shipment is expected to enter each state along the route;

(vi) the estimated time and date of arrival of the shipment at the destination; and

(vii) a point of contact, with a telephone number, for current shipment information.

(C) Revision notice.

(i) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor's designee and to the 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 provide notice as follows of any changes to the information provided in accordance with subparagraphs (B) and (C)(i) of this paragraph.

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

(II) Immediately notify the 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, maintain, and retain 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.

(F) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the NRC or any agreement state, who receive schedule information of the kind specified in subparagraph (B) of this paragraph shall protect that information against unauthorized disclosure as specified in paragraph (10)(D) of this subsection.

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

(A) Shipments by road.

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

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

(II) ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at

all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(III) ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, 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, which must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

(-c-) loss of communications; and

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

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

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

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

(I) use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system

regularly used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

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

(III) use carriers that have established tracking systems that require an authorized signature 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 regularly used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

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

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

(B) The shipping licensee shall notify the agency at (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 at (512) 458-7460 upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

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

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

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

(G) The initial telephonic notification required by subparagraphs (A) - (D) of this paragraph must be followed within a period of 30 days by a written report submitted to the 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 must set forth the following information:

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

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

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

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

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

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

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

(25) Record retention. All records/documents referenced in this subsection shall be made and maintained by the licensee for inspection by the agency in accordance with subsection (mm) of this section. If a retention period is not otherwise specified, these records must be retained until the agency terminates the facility's license. All records related to this subsection may be destroyed upon agency termination of the facility license.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(A) Use carriers which:]

[(i) use package tracking systems;]

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

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

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

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

the shipment;]

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

[(D) Confirm receipt of the shipment; and]

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

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

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

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

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

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

[(A) Establish an expected time of delivery; and]

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

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

[(A) For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.]

[(B) For mobile devices:]

[(i) that are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(iv) access controls;]

[(v) destruction of documents;]

[(vi) use of automatic data processing systems; and]

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

(jj) Appendices.

(1) Subjects to be included in training courses:

(A) (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(ji)(2) [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) (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 **[license]**.

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

(I) the licensee's independent certified public accountant shall have compared the data used by the licensee in the financial test that is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in the financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test; 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) [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 [**ratios**] in clause (ii) of this subparagraph) that was used to obtain the financial assurance instrument used to meet the financial assurance requirement specified in subsection (gg) of this section. However, if the applicant or licensee posted collateral to obtain the financial instrument used to meet the requirement for financial assurance specified in subsection (gg) of this section, the applicant or licensee shall demonstrate financial qualification by one of the methods specified in subclause (II) or (III) of this clause;

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

(III) a self-test (for example, an annual audit report certifying a company's assets and liabilities and resulting ratio as described in clause (ii) of this subparagraph or, in the case of a new company, a business plan specifying expected expenses versus capitalization and anticipated revenues); and [.]

(ii) (No change.)

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

(9) Category 1 and category 2 radioactive materials. Licensees shall use Figure: 25 TAC §289.252(jj)(9) to determine whether a quantity of radioactive material constitutes a Category 1 or Category 2 quantity of radioactive material. [Radionuclide quantities of concern. The following methods shall be used to determine which sources of radioactive material require ICs:]

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

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

[(C) for combinations of radionuclides, include multiple collocated sources of different radionuclides when the aggregate quantities satisfy the following unity

rule: ((amount of radionuclide A) / (quantity of concern of radionuclide A)) + ((amount of radionuclide B) / (quantity of concern of radionuclide B)) + etc..... <1; and]

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

Figure: 25 TAC §289.252(jj)(9) [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 [for 5 years from the date of that service]. The record shall include the date, description of the service, initial survey results, and name(s) of the individual(s) who performed the work.

(3) (No change.)

(mm) Records/documents retention. Each licensee shall make, maintain, and retain at each authorized use site and for the time period set forth in the table, the records/documents described in the following table and in the referenced rule provision, and shall make them available to the agency for inspection, upon reasonable notice.

Figure: 25 TAC §289.252(mm)

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

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

<p>CAUTION-RADIOACTIVE MATERIAL</p> <p>_____</p> <p>(Name of Manufacturer or Distributor);</p>
--

Figure: 25 TAC §289.252(p)(3)(B)

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

_____ ; and
Name of Manufacturer

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	1.0 MCi
H-3	1.0 mCi	1 Ci	10 Ci	100 Ci	10 MCi

Figure: 25 TAC §289.252(jj)(7)

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

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

Category 1 and Category 2 Radioactive Material Thresholds

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

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

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of §289.252(ii) of this title.

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

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

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

R_1 = total activity for radionuclide 1

R_2 = total activity for radionuclide 2

R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1

AR_2 = activity threshold for radionuclide 2

AR_N = activity threshold for radionuclide n

$$\sum_1^n \left[\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \frac{R_n}{AR_n} \right] \geq 1.0$$

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

Rule Cross Reference	Name of Records/Documents	Time Interval for Keeping Record/Document
(ii)(3)(H)(iii)	List of persons approved for unescorted access authorization	3 years after the list is superseded or replaced
(ii)(4)(A)(ii)	Certification in writing that each individual employee's identification was properly reviewed and any documents used for the review	3 years after the date an individual granted unescorted access to category 1 or category 2 quantities of radioactive material no longer requires such access, or, for an individual denied access, 3 years from the date the record was made
(ii)(6)(A)(xii)	Written confirmation of an active federal security clearance from the federal agency or employer that granted the clearance or reviewed the criminal history records check of the individual	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(6)(A)(xiii)	Written verification from a service provider licensee for an individual employed by that service provider that it has conducted a background investigation for the individual and approved that individual for unescorted access to category 1 or category 2 quantities of radioactive material	3 years after the date the individual employee no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(6)(B)	Written confirmation from a federal agency or employer that reviewed the criminal history records check for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material
(ii)(7)(E)	All fingerprint and criminal history records on an individual (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred	3 years after the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material

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

§289.257. Packaging and Transportation of Radioactive Material.

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

(d) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise. To ensure compatibility with international transportation standards, all limits in this section are given in terms of dual units: The International System of Units (SI) followed or preceded by United States (U.S.) standard or customary units. The U.S. customary units are not exact equivalents, but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this section, SI units shall be used.

(1) - (6) (No change.)

(7) Chemical description--A description of the principal chemical characteristics of low-level radioactive waste (LLRW) [a LLRW].

(8) - (18) (No change.)

(19) Freight forwarder--A person or entity which holds itself out to the general public to provide transportation of property for compensation and in the ordinary course of its business:

(A) assembles and consolidates, or provides for assembling and consolidating, shipments and performs break-bulk and distribution operations of the shipments:

(B) assumes responsibility for the transportation from the place of receipt to the place of destination; and

(C) uses for any part of the transportation a rail, motor or water carrier subject to the jurisdiction of either the Federal Motor Carrier Safety Administration or the Surface Transportation Board.

(20) [(19)] Generator--A licensee operating in accordance with an agency, NRC, or agreement state[, or agency] license who:

(A) is a waste generator as defined in this section; or

(B) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

(21) [(20)] Graphite--For the purposes of this section, this means graphite with a boron equivalent content of less than 5 [five] parts per million and density greater than 1.5 grams per cubic centimeter.

(22) [(21)] High integrity container (HIC)--A container commonly designed to meet the structural stability requirements of Title 10, CFR, §61.56, and to meet DOT requirements for a Type A package.

(23) [(22)] Indian tribe--An Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. §479a.

(24) [(23)] Industrial package (IP)--A packaging that, together with its low specific activity (LSA) material or surface contaminated object (SCO) contents, meets the requirements of Title 49, CFR, §173.410 and §173.411. Industrial packages are categorized in Title 49, CFR, §173.411 as either:

- (A) Industrial package Type 1 (IP-1);
- (B) Industrial package Type 2 (IP-2); or
- (C) Industrial package Type 3 (IP-3).

(25) [(24)] Low-level radioactive waste (LLRW)--Radioactive material that meets the following criteria:

(A) LLRW is radioactive material that is:

(i) discarded or unwanted and is not exempt by rule adopted in accordance with the Texas Radiation Control Act (Act), Health and Safety Code, §401.106;

(ii) waste, as that term is defined in Title 10, CFR, §61.2; and

(iii) subject to:

(I) concentration limits established in Title 10, CFR, §61.55, or compatible rules adopted by the agency or the Texas Commission on Environmental Quality (TCEQ), as applicable; and

(II) disposal criteria established in Title 10, CFR, or established by the agency or TCEQ, as applicable.

(B) LLRW does not include:

(i) high-level radioactive waste as defined in Title 10, CFR, §60.2;

(ii) spent nuclear fuel as defined in Title 10, CFR, §72.3;

(iii) byproduct material defined in the Act, Health and Safety Code, §401.003(3)(B);

(iv) naturally occurring radioactive material (NORM) waste that is not oil and gas NORM waste;

(v) oil and gas NORM waste; or

(vi) transuranics greater than 100 nanocuries (3.7 kilobecquerels) per gram (g).

(26) [(25)] Low specific activity (LSA) material--Radioactive material with limited specific activity which is nonfissile or is excepted in accordance with subsection (h) of this section, and which satisfies the following descriptions and limits set forth. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of the following three groups:

(A) LSA-I.

(i) Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores which are not intended to be processed for the use of these radionuclides; or

(ii) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

(iii) Radioactive material for which the A_2 value is unlimited; or

(iv) Other radioactive material (e.g.: mill tailings, contaminated earth, concrete, rubble, other debris, and activated material) in which the radioactivity is distributed throughout, and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with subsection (ee) of this section.

(B) LSA-II.

(i) Water with tritium concentration up to 0.8 terabecquerel per liter (TBq/l) (20.0 curies per liter (Ci/l)); or

(ii) Other material in which the radioactivity is distributed throughout, and the average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

(C) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of Title 10, CFR, §71.77 in which:

(i) the radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

(ii) the radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even with a loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed $0.1 A_2$; and

(iii) the average specific activity of the solid does not exceed $2 \times 10^{-3} A_2/g$.

(27) [(26)] Low toxicity alpha emitters--Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days.

(28) [(27)] Maximum normal operating pressure--The maximum gauge pressure that would develop in the containment system in a period of 1 year under the heat condition specified in Title 10, CFR, §71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

(29) [(28)] Natural thorium--Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

(30) [(29)] Normal form radioactive material--Radioactive material that has not been demonstrated to qualify as special form radioactive material.

(31) [(30)] NRC Forms 540, 540A, 541, 541A, 542, and 542A--Official NRC forms referenced in subsection (ff) of this section which includes the information required by DOT in Title 49, CFR, Part 172. Licensees need not use originals of these forms as long as any substitute forms contain the equivalent information. Licensees may include additional information deemed relevant to the licensee's shipment of low-level radioactive waste. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) or equivalent documents may be completed, transmitted, and stored in electronic media. The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(32) [(31)] Package--The packaging together with its radioactive contents as presented for transport.

(A) Fissile material package, Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package--A fissile material packaging together with its fissile material contents.

(B) Type A package--A Type A packaging together with its radioactive contents. A Type A package is defined and shall comply with the DOT regulations in Title 49, CFR, Part 173.

(C) Type B package--A Type B packaging together with its radioactive contents. On approval by the NRC, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascals (kPa) (100 pounds per square inch (lb/in²)) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in Title 10, CFR, §71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in Title 49, CFR, Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in Title 10, CFR, §71.19.

(33) [(32)] Packaging--The assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

(34) [(33)] Physical description--The items called for on NRC Form 541 to describe a LLRW.

(35) Registered freight forwarder--A freight forwarder that has an emergency plan approved in accordance with subsection (r) of this section and has been issued a registration letter.

(36) Registered shipper--A shipper that has an emergency plan approved in accordance with subsection (r) of this section, and shipping containers approved in accordance with subsection(cc)(8) of this section and been issued a registration letter.

(37) Registered transporter--A transporter that has an emergency plan approved in accordance with subsection (r) of this section, and proof of financial responsibility submitted and approved in accordance with subsection(e)(4) of this section and has been issued a registration letter.

(38) [(34)] Residual waste--LLRW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(39) [(35)] Shipper--The licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers LLRW for transportation, typically consigning this type of waste

to a licensed waste collector, waste processor, or land disposal facility operator. This definition applies only to shipments of LLRW shipped to a Texas LLRW disposal facility.

(40) [(36)] Site of usage--The licensee's facility, including all buildings and structures between which radioactive material is transported and all roadways that are not within the public domain on which radioactive material can be transported.

(41) [(37)] Specific activity of a radionuclide--The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

(42) [(38)] Spent nuclear fuel or spent fuel--Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least 1 year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

(43) [(39)] Surface contaminated object (SCO)--A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. A SCO shall be in one of the following two groups with surface activity not exceeding the following limits:

(A) SCO-I--A solid object on which:

(i) the non-fixed contamination on the accessible surface averaged over 300 square centimeters (cm^2) (or the area of the surface if less than 300 cm^2) does not exceed 4 becquerels per square centimeter (Bq/cm^2) (10^{-4} microcurie per square centimeter ($\mu\text{Ci}/\text{cm}^2$)) for beta and gamma and low toxicity alpha emitters, or $4 \times 10^{-1} \text{ Bq}/\text{cm}^2$ ($10^{-5} \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4 \times 10^4 \text{ Bq}/\text{cm}^2$ ($1 \mu\text{Ci}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or $4 \times 10^3 \text{ Bq}/\text{cm}^2$ ($10^{-1} \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4 \times 10^4 \text{ Bq}/\text{cm}^2$ ($1 \mu\text{Ci}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or $4 \times 10^3 \text{ Bq}/\text{cm}^2$ ($10^{-1} \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters.

(B) SCO-II--A solid object on which the limits for SCO-I are exceeded and on which **[the following limits are not exceeded]**:

(i) the non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $400 \text{ Bq}/\text{cm}^2$ (10^{-2}

$\mu\text{Ci}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters or $40 \text{ Bq}/\text{cm}^2$ ($10^{-3} \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters;

(ii) the fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8 \times 10^5 \text{ Bq}/\text{cm}^2$ ($20 \mu\text{Ci}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or $8 \times 10^4 \text{ Bq}/\text{cm}^2$ ($2 \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters; and

(iii) the non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8 \times 10^5 \text{ Bq}/\text{cm}^2$ ($20 \mu\text{Ci}/\text{cm}^2$) for beta and gamma and low toxicity alpha emitters, or $8 \times 10^4 \text{ Bq}/\text{cm}^2$ ($2 \mu\text{Ci}/\text{cm}^2$) for all other alpha emitters.

(44) Transporter--A carrier who transports radioactive material.

(45) [(40)] Tribal official--The highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(46) [(41)] Uniform Low-Level Radioactive Waste Manifest or uniform manifest--The combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(47) [(42)] Unirradiated uranium--Uranium containing not more than $2 \times 10^3 \text{ Bq}$ ($0.054 \mu\text{Ci}$) of plutonium per gram of uranium-235, not more than $9 \times 10^6 \text{ Bq}$ ($243 \mu\text{Ci}$) of fission products per gram of uranium-235, and not more than $5 \times 10^{-3} \text{ g}$ of uranium-236 per gram of uranium-235.

(48) [(43)] Uranium--Natural, depleted, enriched:

(A) Natural uranium--Uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

(B) Depleted uranium--Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(C) Enriched uranium--Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(49) [(44)] Waste collector--An entity, operating in accordance with an agency, NRC, or agreement state[, or agency] license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(50) [(45)] Waste description--The physical, chemical and radiological description of a LLRW as called for on NRC Form 541.

(51) [(46)] Waste generator--An entity, operating in accordance with an agency, NRC, or agreement state[, or agency] license, who:

(A) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(B) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a waste generator if the transfer of LLRW from its facility is defined as residual waste.

(52) [(47)] Waste processor--An entity, operating in accordance with an NRC or agreement state license, whose principal purpose is to process, repack, or otherwise treat LLRW or waste generated by others prior to eventual transfer of waste to a licensed LLRW land disposal facility.

(53) [(48)] Waste type--A waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically-defined media).

(e) Transportation of radioactive material.

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

(4) Transporter proof of financial responsibility.

(A) Transporters of low-level radioactive waste to a Texas low-level radioactive waste disposal site shall submit proof of financial responsibility required by Title 49, CFR, §387.7 and §387.9, to the agency [agency's Radiation Safety Licensing Branch] and receive a registration letter [approval of this documentation] from the agency prior to initial shipment.

(B) The transporter registration expires on the expiration date of the proof of financial responsibility or in 10 years, if the proof of financial responsibility does not have an expiration date.

(C) To renew a transporter's registration, the transporter shall submit to the agency new proof [Proof] of financial responsibility.

(D) The transporter shall submit to the agency new proof of financial responsibility [shall be submitted after each policy renewal, if] any time the amount of liability coverage is reduced[,] or a new policy is purchased [upon purchase of a new policy].

(5) (No change.)

(f) Exemption for low-level radioactive materials.

(1) (No change.)

(2) Common and contract carriers, freight forwarders, **[and]** warehousemen, and **[who are subject to the rules and regulations of the DOT or]** the United States Postal Service **[(Title 39, CFR, Parts 14 and 15),]** are exempt from the [these] regulations in this subchapter to the extent that they transport or store radioactive material **[sources of radiation]** in the regular course of their carriage for another or storage incident thereto. **[Private carriers who are subject to the rules and regulations of the DOT are exempted from these regulations to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the DOT or the United States Postal Service are subject to applicable sections of these regulations.]**

(3) (No change.)

(g) (No change.)

(h) Exemption from classification as fissile material. Fissile materials meeting the requirements of at least one of the paragraphs (1) through (6) of this subsection are exempt from classification as fissile material and from the fissile material package standards of Title 10, CFR §71.55 and §71.59, but are subject to all other requirements of this section, except as noted.

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

(4) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% **[5 percent]** of the uranium mass.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% **[2 percent]** by mass, with a total plutonium and uranium-233 content not exceeding 0.002% **[0.002 percent]** of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material shall be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20% **[20 percent]** by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(i) - (j) (No change.)

(k) Preliminary determinations. Before the first use of any packaging for the shipment of licensed material the licensee shall:

(1) (No change.)

(2) where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, test the containment system at an internal pressure at least 50% **[50 percent]** higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(3) (No change.)

(l) - (n) (No change.)

(o) Records. For a period of 3 **[three]** years after shipment, each licensee shall maintain, for inspection by the agency, a record of each shipment of radioactive material including **[showing]** the following where applicable:

(1) - (8) (No change.)

(p) Reports. The transporter and shipper shall immediately report by telephone, **[telegram, mailgram, or]** facsimile, or other electronic media transmission, all radioactive waste transportation accidents to the agency and the local emergency planning committees in the county where the radioactive waste accident occurs. All other accidents involving radioactive material shall be reported in accordance with §289.202(xx) and (yy) of this title.

(q) Advance notification of transport of irradiated reactor fuel and certain radioactive waste.

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

(3) Advanced notification is also required under this subsection for the shipment **[shipments]** of licensed radioactive material, other than irradiated fuel, meeting the following three conditions:

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

(4) The following are procedures for submitting advance notification:

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

(D) The licensee shall make, maintain and retain a copy of the notification for inspection by the agency as a record for 3 **[three]** years.

(5) - (7) (No change.)

(r) Emergency plan registration requirements.

(1) Each shipper and transporter of radioactive waste shall submit [adopt] an emergency plan to the agency and receive a registration letter from the agency prior to initial shipment [approved by the agency for responding to transportation accidents].

(2) A freight forwarder must submit an emergency plan in order to become a registered freight forwarder.

(3) Each shipper, transporter or freight forwarder applying for registration shall submit a Business Information Form (RC 252-1).

(4) Shipper and freight forwarder registrations expire 10 years from the date of issuance. New documentation to renew the registration must be submitted at least 30 days prior to the expiration date.

(s) Quality assurance requirements.

(1) Purpose. This subsection describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.

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

(C) The licensee, certificate holder, and applicant for a CoC are responsible for the following:

(i) (No change.)

(ii) the quality assurance provision applicable [provisions which applies] to its use of a packaging for the shipment of licensed material under subsections (s) - (bb) and (ee) of this section [subject to this subpart].

(2) - (4) (No change.)

(t) - (bb) (No change.)

(cc) Transfer for disposal and manifests.

(1) - (7) (No change.)

(8) Each shipper shall submit a list for approval by the agency of shipping containers that they intend to use to ship LLRW to the Texas LLRW site. If the shipper is licensed in Texas and is the holder of a CoC, the shipper shall also submit written documentation of its program for quality assurance and control and handling, shipping and control measures that comply with the requirements of subsections (s), (t), and (v) - (bb) of this section.

(dd) Fees.

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

(3) Money expended from the agency's Radiation and Perpetual Care Account to respond to accidents involving LLRW shall be reimbursed to the agency's Radiation and Perpetual Care Account by the responsible shipper or transporter according to this section **[rules adopted by the board]**.

(4) - (5) (No change)

(ee) - (ff) (No change.)