

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) - (21) (No change.)

(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.

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

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

(25) [(24)] 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.

(26) [(25)] 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.

(27) [(26)] 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)).

(28) [(27)] 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.

(29) [(28)] 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.

(30) [(29)] 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.

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

(32) [(31)] 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.

(33) [(32)] 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.

(34) [(33)] 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.

(35) [(34)] 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) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

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

(37) [(36)] 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.

(38) [(37)] 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.

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

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

(41) [(40)] 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.

(42) [(41)] Generally applicable environmental radiation standards--Standards issued by the United States Environmental Protection Agency (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.

(43) [(42)] 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.

(44) [(43)] 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.

(45) [(44)] 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.

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

(47) [(46)] 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.

(48) [(47)] 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.

(49) [(48)] 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.

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

(51) [(50)] 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.

(52) [(51)] 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.

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

(54) [(53)] 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.

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

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

(57) [(56)] 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.

(58) [(57)] 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.

(59) [(58)] 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), 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, 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.

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

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

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

(63) [(62)] 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.

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

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

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

(67) [(66)] 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.

(68) [(67)] 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 MeV.

(69) [(68)] 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.

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

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

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

(73) [(72)] 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.

(74) [(73)] 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.

(75) [(74)] 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.

(76) [(75)] 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.

(77) [(76)] 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 gray).

(78) [(77)] 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.

(79) [(78)] 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.

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

(81) [(80)] 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).

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

(83) [(82)] Radioactive waste--As used in §289.254 of this title (relating to Licensing of Radioactive Waste Processing and Storage Facilities), this term is equivalent to LLRW.

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

(85) [(84)] Radiobioassay (See definition for bioassay.)

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

(87) [(86)] Regulation (See definition for rule.)

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

(89) [(88)] 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)).

(90) [(89)] 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.

(91) 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.

(92) [(90)] 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 30, Texas Administrative Code, §336.334.

(93) [(91)] 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.

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

(95) [(93)] 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."

(96) [(94)] 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 under the most severe conditions that are likely to be encountered in normal use and handling.

(97) [(95)] 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) [**averaged over an area of 1 square centimeter (cm^2)**].

(98) [(96)] SI--The abbreviation for the International System of Units.

(99) [(97)] 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 ($1 \text{ Sv} = 100 \text{ rem}$).

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

(101) [(99)] 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.

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

(103) [(101)] 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.

(104) [(102)] Special nuclear material--Special nuclear material is defined as:

(A) plutonium, uranium-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.

(105) [(103)] 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)(105)(B) [Figure: 25 TAC §289.201(b)(103)(B)]

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

(107) [(105)] 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.

(108) [(106)] 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.

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

(110) [(108)] Texas Regulations for Control of Radiation (TRCR)--All sections of Title 25 Texas Administrative Code (TAC), Chapter 289.

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

(112) [(110)] 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.

(113) [(111)] 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 10 CFR 71.59, whichever is larger.

(114) [(112)] 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(ff) of this title (relating to Packaging and Transportation of Radioactive Material) or may be determined by procedures described in §289.257(ff) of this title.

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

(116) [(114)] Unrefined and unprocessed ore--Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(117) [(115)] 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.

(118) [(116)] 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 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.

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

(120) [(118)] 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 (15)(B) - (E) of this subsection.

(121) [(119)] Week--Seven consecutive days starting on Sunday.

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

(123) [(121)] 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.

(124) [(122)] 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 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.

(125) [(123)] 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.

(126) [(124)] 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) - (o) (No change.)

Figure: 25 TAC §289.201(b)(105)(B)

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