

25 TEXAS ADMINISTRATIVE CODE

§289.251

Exemptions, General Licenses, and General Licenses Acknowledgments

Texas Regulations for Control of Radiation

(revisions effective September 24, 2018, are shown as shaded text)

	<u>Page</u>
§289.251(a)	Purpose..... 251-1
§289.251(b)	Scope..... 251-1
§289.251(c)	Definitions..... 251-1
§289.251(d)	Exemptions for Source Material..... 251-1
§289.251(e)	Exemptions for Radioactive Material other than Source Material..... 251-5
§289.251(e)(1)	Exempt Concentrations..... 251-5
§289.251(e)(2)	Exempt Quantities..... 251-6
§289.251(e)(3)	Exempt Items..... 251-7
§289.251(e)(3)(A)	Certain Items Containing Radioactive Material..... 251-7
§289.251(e)(3)(B)	Self-luminous Products Containing Tritium, Krypton-85, Promethium-147, or Radium-226..... 251-10
§289.251(e)(3)(C)	Gas and Aerosol Detectors Containing Radioactive Material..... 251-11
§289.251(e)(3)(D)	Certain Industrial Devices..... 251-12
§289.251(e)(4)	Exemption for Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans..... 251-12
§289.251(f)	General Licenses..... 251-13
§289.251(f)(1)	Compliance History..... 251-13
§289.251(f)(2)	Modification, Suspension, and Revocation of a General License..... 251-13
§289.251(f)(3)	General Licenses for Source Material..... 251-14
§289.251(f)(4)	General Licenses for Radioactive Material Other Than Source Material..... 251-19
§289.251(f)(4)(A)	General Licenses for Static Elimination Devices and Ion Generating Tubes..... 251-19
§289.251(f)(4)(B)	General License for Luminous Safety Devices for Aircraft..... 251-19
§289.251(f)(4)(C)	General License for Ownership of Radioactive Material..... 251-20
§289.251(f)(4)(D)	General License for Calibration, Stabilization, and Reference Sources..... 251-20
§289.251(f)(4)(E)	General License for Ice Detection Devices..... 251-22

25 TAC §289.251

**Exemptions, General Licenses, and General Licenses Acknowledgments
(Continued)**

	<u>Page</u>
§289.251(f)(4)(F)	General License for Intrastate Transportation of Radioactive Material.....251-23
§289.251(f)(4)(G)	General License for the Use of Radioactive Material for Certain <i>In Vitro</i> Clinical or Laboratory Testing, Not to Include Research and Development.....251-24
§289.251(f)(4)(H)	General License for Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.....251-27
§289.251(f)(4)(I)	General License does not Authorize the Manufacture or Import of Devices Containing Radioactive Material.....251-33
§289.251(f)(4)(J)	Written Instructions shall be Followed While Performing the Testing and shall be Maintained for Inspection by the Agency.....251-33
§289.251(f)(4)(K)	General License for Certain Items and Self-Luminous Products Containing Radium-226.....251-33
§289.251(g)	General License Acknowledgements for Radioactive Material other than Source Material.....251-35
§289.251(h)	Issuance of General License Acknowledgments.....251-36
§289.251(i)	Specific Terms and Conditions.....251-37
§289.251(j)	Termination of General License Acknowledgements.....251-38
§289.251(k)	Amendment of General License Acknowledgements.....251-38
§289.251(l)	APPENDICES251-38
§289.251(l)(1)	Exempt Concentrations.....251-39
§289.251(l)(2)	Exempt Quantities.....251-45

25 TEXAS ADMINISTRATIVE CODE

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

(a) Purpose. This section provides for exemptions to licensing requirements, general licensing of radioactive material, and acknowledgement of general licenses.

(b) Scope. Except as otherwise authorized, no person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a general license or general license acknowledgement issued in accordance with this section, or in a specific license issued in accordance with §289.252 of this title (relating to Licensing of Radioactive Material), §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), §289.258 of this title (relating to Licensing and Radiation Safety Requirements for Irradiators), or §289.259 of this title (relating to Licensing of Naturally Occurring Radioactive Material (NORM)).

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

(1) General license--An authorization in accordance with this section that grants authority to a person for certain activities involving radioactive material, and is effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons. The general licensee is subject to all other applicable portions of this chapter and any limitations of the general license.

(2) General license acknowledgement--A written recognition of a general license issued in accordance with this section. The issuance of a general license acknowledgement requires the submission of an application to the agency. A written acknowledgement of a general license granted in accordance with this section is issued by the agency. The holder of a general license acknowledgement is subject to all other applicable portions of this chapter as well as any conditions specified in the acknowledgement document.

(d) Exemptions for source material.

§289.251(d)(1)

(1) Any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1.0% (0.05%) of the mixture, compound, solution, or alloy.

(2) Any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore. This exemption does not apply to the mining of ore containing source material.

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

(A) any quantities of thorium contained in:

(i) incandescent gas mantles;

(ii) vacuum tubes;

(iii) welding rods;

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams (mg) of thorium;

(v) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;

(vi) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 mg of thorium;

(B) source material contained in the following products:

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

§289.251(d)(3)(B)(ii)

(ii) glassware containing not more than 2% 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) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

(iv) piezoelectric ceramic containing not more than 2.0% by weight source material;

(C) photographic film, negatives, and prints containing uranium or thorium;

(D) any finished product or part fabricated of, or containing, metal-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(E) 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) 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 impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," required at that time);

(ii) 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 impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM" required at that time); and

§289.251(d)(3)(E)(iii)

(iii) 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;

(F) natural or depleted uranium used as shielding constituting part of any shipping container, provided that:

(i) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM;" and

(ii) the uranium metal is encased in a one-eighth inch minimum wall thickness of mild steel or equally fire resistant material;

(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) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4.0% by weight.

(4) The exemptions in subsection (d)(3) of this section do not authorize the manufacture of any of the products described.

§289.251(d)(5)

(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) Except as provided in subparagraph (B) of this paragraph, any person is exempt from this section and §289.252 of this title if that person receives, possesses, uses, transfers, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in subsection (l)(1) of this section.

(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, except in accordance with a specific license issued under §289.252(i) of this title.

§289.251(e)(1)(C)

(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 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) Except as provided in subparagraphs (C), (D), and (F) of this paragraph, any person is exempt from these rules if that person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in subsection (l)(2) of this section.

(B) Any person who possesses radioactive material received or acquired, prior to September 25, 1971, in accordance with the general license provided in subsection (f)(4)(A) of this section is exempt from the requirements for a license set forth in §289.252 of this title if that person possesses, uses, transfers, or owns such radioactive material.

(C) This paragraph does not authorize the production, packaging, or repackaging **or transfer** of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(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, 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.

§289.251(e)(2)(E)

(E) The schedule of quantities set forth in subsection (I)(2) of this section applies only to radioactive materials distributed as exempt quantities under a specific license issued by the agency, the NRC, or any agreement state. Subsection (I)(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 from the licensing requirements in this section or §289.252 of this title.

(F) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in subsection (I)(2) of this section, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the requirements in this title.

(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, or persons who initially transfer for sale or distribution the following products containing radioactive material, 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-) 25 millicuries (mCi) (925 megabecquerels (MBq)) of tritium per timepiece;

(-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;

§289.251(e)(3)(A)(i)(I)(-f-)

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

(-g-) the levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter (mg/cm^2) of absorber:

(-1-) for wrist watches, 0.1 millirad per hour (mrad/hr) at 10 centimeters (cm) from any surface;

(-2-) for pocket watches, 0.1 mrad/hr at 1 cm from any surface; and

(-3-) for any other timepiece, 0.2 mrad/hr at 10 cm from any surface; or

(-h-) 1 μCi (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to **November 30, 2007**;

(II) static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μCi (18.5 MBq) of polonium-210 per device;

(III) ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μCi (18.5 MBq) of polonium-210 per device or of a total of not more than 50 mCi (1.85 gigabecquerels (GBq)) of hydrogen-3 (tritium) per device;

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

(V) 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;

§289.251(e)(3)(A)(i)(VI)

(VI) 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) 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 µCi (0.037 MBq) of cobalt-60;

(-c-) 5 µCi (0.185 GBq) of nickel-63;

(-d-) 30 µCi (1.11 GBq) of krypton-85;

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

(-f-) 30 µCi (1.11 GBq) of promethium-147;

(VIII) 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 (I)(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 (I)(2) of this section, provided that the sum of such fractions shall not exceed unity.

§289.251(e)(3)(A)(i)(IX)

(IX) 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) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, DC 20555.

(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, 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) Self-luminous products containing tritium, krypton-85, or promethium-147.

(i) Except for persons who manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in clause (iii) of this subparagraph, any person is exempt from this chapter if that person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.22, which authorizes the initial transfer of the product to persons who are exempt from regulatory requirements.

(ii) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under clause (i) of this subparagraph, **should** apply for:

(I) a specific license to be issued by the NRC in accordance with Title 10, CFR, §32.22; and

(II) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

§289.251(e)(3)(B)(iii)

(iii) The exemption in clause (i) of this subparagraph does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(C) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property.

(I) Detectors containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC in accordance with Title 10, CFR, §32.26.

(II) The specific license issued by the NRC in accordance with Title 10, CFR, §32.26, authorizes the initial transfer of the product for use to persons who are exempt from regulatory requirements.

(III) This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued in accordance with §289.252 of this title or under comparable provisions to Title 10, CFR, §32.26 authorizing distribution to persons exempt from regulatory requirements.

(IV) Any person who desires to manufacture, process, or produce, gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under this clause, shall apply for:

(-a-) a specific license to be issued by the NRC in accordance with Title 10, CFR, §32.26; and

(-b-) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

(ii) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, DC 20555.

§289.251(e)(3)(C)(iii)

(iii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by any agreement 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) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere.

(i) Devices containing radioactive material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued under Title 10, CFR, §32.30.

(ii) The specific license issued by the NRC in accordance with Title 10, CFR, §32.30, authorizes the initial transfer of the device for use under Title 10, CFR, §32.30.

(iii) This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(iv) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under this subparagraph, shall apply for:

(I) a license to be issued by the NRC under Title 10, CFR, §32.30; and

(II) a certificate of registration to be issued by the NRC in accordance with Title 10, CFR, §32.210.

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

§289.251(e)(4)(A)

(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) 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) A person desiring to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance with §289.256 of this title.

(C) A person desiring to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license in accordance with Title 10, CFR, §32.21.

(D) Nothing in this subsection relieves a person from complying with applicable requirements of the United States Food and Drug Administration (FDA) and other federal and state requirements governing the receipt, administration, and use of drugs.

(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, §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 agency actions have been issued against the general licensee, within the previous 6 years, that assess administrative or civil penalties against the general licensee, or that revoke or suspend the general license.

(2) Modification, suspension, and revocation of a general license.

(A) The terms and conditions of all general licenses shall be subject to revision or modification.

§289.251(f)(2)(B)

(B) A general license may be suspended or revoked by reason of amendments to the Texas Radiation Control Act (Act), Health and Safety Code, Chapter 401, by reason of rules in this chapter, or orders issued by the agency.

(C) Any general license may be revoked, suspended, or modified, in whole or in part, for any of the following:

(i) any material false statement in the application for a general license acknowledgement or any statement of fact required in accordance with provisions of the Act;

(ii) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a general license on an original application;

(iii) violation of, or failure to observe, any of the terms and conditions of the Act, this chapter, or of the general license, or order of the agency; or

(iv) existing conditions that constitute a substantial threat to the public health or safety or the environment.

(D) Except in cases in which the occupational and public health, or safety requires otherwise, no general license shall be suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct that may warrant such action shall have been called to the attention of the holder of the general license in writing and the holder of the general license shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

(E) Each general license revoked by the agency expires at the end of the day on the date of the agency's final determination to revoke the general license, or on the revocation date stated in the determination, or as otherwise provided by agency order.

(3) General licenses for source material.

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

§289.251(f)(3)(A)(i)

(i) 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, 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

§289.251(f)(3)(A)(i)(IV)

(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.

(ii) Any person who receives, possesses, uses, or transfers source material in accordance with the general license in clause (i) of this subparagraph:

(I) is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings 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.

§289.251(f)(3)(A)(iii)

(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 clause (i) of this subparagraph is exempt from the regulations in §§289.201, 289.202, and 289.203 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) A general license is issued to own source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(C) A general license is issued to mine, transport, and transfer ores containing source material without regard to quantity. In addition to the provisions of subsection (f) of this section, persons who mine, transport, and transfer ores containing source material in accordance with this section shall comply with the provisions of §289.202(n) and (ff) of this title.

§289.251(f)(3)(D)

(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 clauses (i) - (iv) of this subparagraph.

(i) The general license in this paragraph applies only to products or devices that have been manufactured either in accordance with a specific license issued by the agency to the manufacturer of the products or devices in accordance with §289.252(s) of this title or in accordance with a specific license issued to the manufacturer by another agreement state or the NRC that authorizes manufacture of the products or devices for distribution to persons generally licensed by another agreement state or the NRC.

(ii) Persons who receive, acquire, possess, or use depleted uranium in accordance with the general license in this paragraph shall notify the agency within 30 days after the first receipt of acquisition of such depleted uranium. The general licensee shall furnish the following information and such other information as may be required by the agency:

(I) name and address of the general licensee;

(II) a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium in accordance with this paragraph and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(III) name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in clause (ii) of this subparagraph.

(iii) The general licensee possessing or using depleted uranium in accordance with the general license in this paragraph shall report in writing to the agency any changes in information furnished by the general licensee. The report shall be submitted within 30 days after the effective date of such change.

(iv) A person who receives, acquires, possesses, or uses depleted uranium in accordance with the general license in this paragraph:

(I) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

§289.251(f)(3)(D)(iv)(II)

(II) shall not abandon such depleted uranium;

(III) shall transfer or dispose of such depleted uranium only in accordance with the provisions of §289.252(cc) of this title. In the case where the transferee receives the depleted uranium in accordance with the general license in this paragraph or equivalent rule of the NRC or an agreement state, the transferor shall furnish the transferee a copy of this paragraph;

(IV) within 30 days of transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium in accordance with such transfer; and

(V) shall not export such depleted uranium except in accordance with a license issued by the NRC in accordance with Title 10, CFR, Part 110.

(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 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.

§289.251(f)(4)(B)(i)

(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) each device has been manufactured, assembled, or initially transferred in accordance with a specific license issued by the NRC, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state that authorizes the manufacture or assembly of the device to persons generally licensed by the agency or an agreement state.

(ii) The general license in clause (i) of this subparagraph does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(iii) The general license in clause (i) of this subparagraph does not authorize the receipt, acquisition, possession, or use of tritium or promethium-147 contained in instrument dials.

(C) General license for ownership of radioactive material. A general license is issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this section, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

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

(i) A general license is issued to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of clauses (ii) and (iii) of this subparagraph, americium-241, plutonium, and/or radium-226, in the form of calibration, stabilization, or reference sources to any person who holds a specific license issued by the:

(I) agency that authorizes that person to receive, possess, use, and transfer radioactive material; and

(II) NRC that authorizes that person to receive, possess, use, and transfer radioactive material.

§289.251(f)(4)(D)(ii)

(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, 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 μ Ci (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-) option 1, as appropriate:

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION RADIOACTIVE MATERIAL THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM-238) (PLUTONIUM-239)*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____; or
Name of Manufacturer or Initial Transferor

* Showing only the name of the appropriate material

§289.251(f)(4)(D)(iii)(II)(-b-)

(-b-) option 2, as appropriate:

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

(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 agreement state to receive the source;

(IV) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium-238, plutonium-239, or radium-226 that might otherwise escape during storage; and

(V) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(iv) The general license in subparagraph (A) of this paragraph does not authorize the manufacture of calibration or reference sources containing americium-241, plutonium-238, plutonium-239, or radium-226.

(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.

§289.251(f)(4)(E)(ii)

(ii) Persons who receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices in accordance with the general license in clause (i) of this paragraph shall do the following:

(I) upon occurrence of visually observable damage, such as bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the NRC or an agreement state to manufacture or service such devices; or dispose of the device by transfer to a person authorized by a specific license from the agency, the NRC, or an agreement state; and

(II) assure that all labels affixed to the device at the time of receipt, and which bear a statement prohibiting removal of the labels, are maintained on the device.

(iii) The general license in subparagraph (A) of this paragraph does not authorize the manufacture, assembly, disassembly, or repair of strontium-90 in ice detection devices.

(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(ww) - (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(ww) - (yy) of this title.

§289.251(f)(4)(G)

(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 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;

§289.251(f)(4)(G)(i)(VII)

(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) The general licensee shall store the radioactive material in the original shipping container or in a container providing equivalent radiation protection and meeting the requirements of §289.202(cc) of this title until used.

(III) The general licensee shall use the radioactive material only for the uses authorized by clause (i) of this subparagraph.

(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, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(V) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in clause (i)(VII) of this subparagraph as required by §289.202(ff) of this title.

(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:

§289.251(f)(4)(G)(iii)(I)

(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 of a specific license issued by the NRC or any agreement 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-) option 1, as appropriate:

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 the regulations and a general license of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____ ; or
Name of Manufacturer

(-b-) option 2, as appropriate:

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

§289.251(f)(4)(G)(iv)

(iv) No person shall receive, acquire, possess, use, or transfer radioactive material in accordance with the general license in clause (i) of this subparagraph until that person has filed an application for registration on a form prescribed by the agency and has received from the agency a notification of receipt with an assigned registration number. The applicant shall submit the following information and any other information as may be required by the agency:

(I) name and address of the physician, veterinarian, clinical laboratory, or hospital;

(II) the location of use; and

(III) a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized in accordance with clause (i) of this subparagraph, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

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

(i) A general license is issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and state or local government agencies to receive, acquire, possess, use, or transfer in accordance with the provisions of clauses (ii) - (iv) of this subparagraph, radioactive material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.

(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:

(I) a specific license issued by the agency in accordance with §289.252(l) of this title;

§289.251(f)(4)(H)(ii)(II)

(II) a specific license issued by the NRC or any agreement state that authorizes distribution of devices to persons generally licensed by the NRC or any agreement state; or

(III) an equivalent specific license issued by a state with provisions comparable to §289.252(l) of this title.

(iii) The devices must have been received from a specific licensee described in clause (ii) of this subparagraph or through a transfer made in accordance with clause (iv)(XII) of this subparagraph.

(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) assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained on the device and are clearly visible and legible. The general licensee shall comply with all instructions and precautions provided by such labels;

(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 intervals or at such other intervals as specified in the label; however:

(-a-) devices containing only krypton need not be tested for leakage of radioactive material; and

(-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;

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

(-a-) in accordance with the instructions provided by the labels;

§289.251(f)(4)(H)(iv)(III)(-b-)

(-b-) in accordance with written instructions provided by the manufacturer as specified in §289.252(l)(3) of this title; or

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

(IV) maintain records for inspection by the agency documenting compliance with the requirements of subclauses (II) and (III) of this clause. The records shall include 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 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 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 years from the date of the recorded event or until the device is transferred or disposed of;

(V) maintain assignment records (utilization records) for portable or mobile devices for inspection by the agency at the location listed in the general license acknowledgement in accordance with subsection (g) of this section. These records shall include:

(-a-) a unique identification (for example, serial number) of each portable or mobile device;

(-b-) the location(s) where each portable or mobile device is assigned; and

§289.251(f)(4)(H)(iv)(V)(-c-)

(-c-) the date(s) each portable or mobile device is assigned to the location(s) in accordance with item (-b-) of this subclause;

(VI) have a copy of the appropriate operating and instruction manual at each temporary site for agency inspection;

(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 (0.005 μ Ci) 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 agreement 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 (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) not abandon the device containing radioactive material;

(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 agreement 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-) identification of the device by manufacturer's (or initial transferor's) name, model and serial number;

(-b-) name, address, and license number of the person receiving the device; and

§289.251(f)(4)(H)(iv)(X)(-c-)

(-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 its own specific license without prior approval, if, the holder:

(-a-) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(-b-) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by clause (iv)(I) of this subparagraph) so that the device is labeled in compliance with §289.202(cc) of this title; however the manufacturer, model number, and serial number must be retained;

(-c-) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

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

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

(-a-) the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this section and any safety documents identified in the label on the device. Within 30 days of the transfer, the transferor shall report the following to the agency:

(-1-) manufacturer's (or initial transferor's) name;

(-2-) model and serial number of the device transferred;

(-3-) transferee's name and mailing address for the location of use; and

(-4-) name, title, and phone number of the responsible individual identified by the transferee in accordance with subclause (XIII) of this clause to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

§289.251(f)(4)(H)(iv)(XII)(-b-)

(-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) appoint an individual responsible for having knowledge of the appropriate agency requirements and the authority for taking required actions to comply with appropriate agency requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate agency requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(XIV) report changes to the mailing address for the location of use (including change in name of general licensee) to the agency within 30 days of the effective date of the change. If it is a portable device, a report of address change is only required for a change in the device's primary place of storage;

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

(-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 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 quarterly physical inventories of these devices while they are in standby. The licensee shall make, maintain, and retain for intervals of 5 years, records of the quarterly physical inventories for inspection by the agency;

(XVI) not export the device containing radioactive material except in accordance with Title 10, CFR, Part 110;

§289.251(f)(4)(H)(iv)(XVII)

(XVII) comply with the provisions of §289.202(w) and (xx) of this title for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of §289.202 and §289.203 of this title;

(XVIII) respond to written requests from the agency 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 a written justification for the request; and

(XIX) assure that the device is used in accordance with information contained in the device safety evaluation.

(I) The general license in subparagraph (H) of this paragraph does not authorize the manufacture or import of devices containing radioactive material.

(J) The written instructions specified in subparagraph (H)(iv)(III)(-a-) and (-b-) of this paragraph shall be followed while performing the testing and the written instructions in subparagraph (H)(iv)(III)(-b-) of this paragraph shall be maintained for inspection by the agency.

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

(i) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer radium-226 contained in the following products manufactured prior to November 30, 2007.

(I) Antiquities originally intended for use by the general public. For purposes of this subclause, antiquities are products distributed for use by the general public in the late 19th and early 20th centuries; such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(II) Intact timepieces containing greater than 1 μCi (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(III) Luminous items installed in air, marine, or land vehicles.

§289.251(f)(4)(K)(i)(IV)

(IV) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(V) Small radium sources containing no more than 1 μCi (0.037 MBq) of radium 226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(ii) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in clause (i) of this subparagraph are exempt from the provisions of §§289.201, 289.202, 289.203, and 289.252 of this title, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under §289.252 of this title.

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

(I) Provide to the agency within 30 days of any indication of possible damage to the product that could result in a loss of the radioactive material. The report should include a brief description of the event, and the remedial action taken.

(II) Not abandon products containing radium-226.

(-a-) The product, and any radioactive material from the product, may only be disposed of according to §289.202 of this title or as otherwise approved by the agency.

(-b-) The product, and any radioactive material from the product, may be transferred to a person authorized by a specific license to receive the radium-226 or as otherwise approved by the agency.

(III) The general license in this subparagraph does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired provided that paint containing radium-226 is not applied or removed.

§289.251(f)(4)(K)(iii)(IV)

(IV) Not export products containing radium-226 except in accordance with or equivalent regulations of the NRC Title 10, CFR, §110.

(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 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 a written justification for the request.

(g) General license acknowledgements for radioactive material other than source material. In addition to the requirements of this section, all general license acknowledgement holders, unless otherwise specified, are subject to the requirements of §§289.201, 289.202(w) and (xx), 289.204, 289.205, and 289.257 of this title.

(1) Persons possessing a general license for devices in accordance with subsection (f)(4)(H) of this section and being in the possession of radioactive material in devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, 37 MBq (1 mCi) of americium-241, or any transuranic (for example, element with atomic number greater than uranium (92)), based on the activity indicated on the label on the device, shall file an application for acknowledgement within 30 days of receipt, acquisition, or possession of such a device. The application shall be on a form prescribed by the agency to include the following information and any other information specifically requested by the agency:

(A) name and mailing address of the general licensee;

(B) information about each device to include the manufacturer (or initial transferor), model number, and serial number of the device, and the radioisotope and activity (as indicated on the label), and serial number of the source;

§289.251(g)(1)(C)

(C) name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with subsection (f)(4)(H)(iv)(XIII) of this section;

(D) address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;

(E) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;

(F) certification by the responsible representative of the general licensee that they are aware of the requirements of this section; and

(G) a completed RC Form 252-1, Business Information Form and the applicable fee as required by §289.204 of this title.

(2) Persons generally licensed by the agency, **the NRC, or any agreement state** with respect to devices meeting the criteria in paragraph (1) of this subsection, are not subject to the requirements of paragraph (1) of this subsection if the devices are used in areas subject to agency jurisdiction for a period less than 180 days in any calendar year.

(3) Persons possessing a device meeting the criteria of paragraph (1) of this subsection shall respond annually to the General License Acknowledgement Self Evaluation Form provided by the agency. The form shall be completed in accordance with the instructions contained in the form. The completed form shall be submitted to the agency within 30 days of receipt.

(4) **Each address for a location of use, as described under paragraph (1)(D) of this subsection, represents a separate general licensee and requires a separate registration and fee.**

(h) Issuance of general license acknowledgements.

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

§289.251(h)(2)

(2) The agency may incorporate in any general license acknowledgement at the time of issuance, or thereafter by amendment, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this section as the agency deems appropriate or necessary in order to:

(A) minimize danger to occupational and public health and safety or the environment;

(B) require reports and the keeping of records, and to provide for inspections of activities in accordance with the license as may be appropriate or necessary; and

(C) prevent loss or theft of material subject to this section.

(3) The agency may request, and the licensee shall provide, additional information after the general license acknowledgement has been issued to enable the agency to determine whether the general license acknowledgement should be modified in accordance with subsection (k) of this section.

(i) Specific terms and conditions.

(1) Each general license acknowledgement issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the agency.

(2) Each person holding a general license acknowledgement issued by the agency in accordance with this section shall confine use and possession of the devices and radioactive material identified in the general license acknowledgement to the locations specified in the general license acknowledgement. Radioactive material shall not be used or stored in residential locations unless authorized by the agency. Each person holding a general license acknowledgement issued by the agency shall obtain prior approval from the agency before storing or using radioactive material in an area not previously authorized in the general license acknowledgement.

(3) Each holder of a general license acknowledgement shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the general license acknowledgement holder or its parent company.

(4) The notification in paragraph (3) of this subsection shall include:

§289.251(i)(4)(A)

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the date of the filing of the petition.

(5) A copy of the "Petition for Bankruptcy" shall be submitted to the agency with the written notification.

(j) Termination of general license acknowledgements.

(1) Each holder of a general license acknowledgement shall notify the agency immediately, in writing, and request termination of the general license acknowledgement when the holder of the general license acknowledgement decides to terminate all activities involving materials specified in the general license acknowledgement.

(2) Each holder of a general license acknowledgement shall, no less than 30 days before vacating or relinquishing possession of control of premises that have been used as a place of storage or use of radioactive material as a result of general licensed activities, notify the agency in writing of intent to vacate and do the following:

(A) terminate use of radioactive material;

(B) dispose of radioactive material in accordance with this section and/or §289.202(ff) of this title; and

(C) pay any outstanding fees in accordance with §289.204 of this title.

(k) Amendment of general license acknowledgements.

(1) The holder of the general license acknowledgement required by subsection (g)(1) of this section shall report in writing to the agency any changes in information furnished by the holder of the general license acknowledgement. The report shall be submitted within 30 days after the effective date of such change.

(2) Applications for amendments of a general license acknowledgement shall be filed in accordance with subsection (g)(1)(A) - (F) of this section, as applicable, and shall specify the respects in which the holder of a general license acknowledgement desires a general license acknowledgement to be amended.

(l) Appendices.

§289.251(l)(1)

(1) Exempt concentrations.

		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

§289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration μCi/ml*	Liquid and Solid Concentration μCi/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.

** μCi/gm for solids

§289.251(l)(1)

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

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

** μCi/gm for solids

§289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration μCi/ml*	Liquid and Solid Concentration μCi/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.

** μCi/gm for solids

§289.251(l)(1)

		Column I	Column II
Element (atomic number)	Isotope	Gas Concentration μCi/ml*	Liquid and Solid Concentration μCi/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	
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}

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

** μCi/gm for solids

§289.251(l)(1)

		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

(2) Exempt quantities.

<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

§289.251(l)(2)

<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