# Title 33

# ENVIRONMENTAL QUALITY

## Part XV. Radiation Protection

### Chapter 1. General Provisions

### §102. Definitions and Abbreviations

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain chapter may be found in that Chapter.

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*Accelerator-Produced Material*—~~any material made radioactive by a particle accelerator.~~Repealed.

*Accelerator-Produced Radioactive Material*—any material made radioactive by a particle accelerator.

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*Byproduct Material*—

1. any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;~~ and~~

2. the tailings or wastes produced by the extraction or concentration of uranium or thorium (R.S. 30:2103) from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition~~.~~;

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

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

5. any discrete source of naturally occurring radioactive material, other than source

material that the Commission, in consultation with the administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and before, on, or after August 8, 2005, is extracted or converted after extraction for the use in a commercial, medical, or research activity.

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*Consortium*—an association of medical use licensees and a *Positron Emission Tomography (PET) radionuclide production facility* as defined in this Section located in the same geographical area. They shall jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for *medical use* as defined in this Section. The PET radionuclide production facility within the consortium shall be located at an educational institution, a federal facility, or a medical facility.

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*Discrete Source*—a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

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*Particle Accelerator*—any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of ~~1 million electron volts~~1 megaelectron volt.

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*Positron Emission Tomography (PET) Radionuclide Production Facility*—a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

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*Waste*—those low-level radioactive wastes that are acceptable for disposal in a land disposal facility.

For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste:

1. not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11.e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and in the definition of *byproduct material* of this Section; and

2. …

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HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), LR 19:1421 (November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), LR 24:2089 (November 1998), repromulgated LR 24:2242 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2563 (November 2000), LR 26:2767 (December 2000), LR 30:1171, 1188 (June 2004), amended by the Office of Environmental Assessment, LR 31:44 (January 2005), LR 31:1064 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:811 (May 2006), LR 32:1853 (October 2006), LR 33:1016 (June 2007), LR 33:2175 (October 2007), LR 34:982 (June 2008), LR 36:1771 (August 2010), amended by the Office of the Secretary, Legal Division, LR 38:2748 (November 2012), LR 40:283 (February 2014).

**Chapter 3. Licensing of Radioactive Material**

**Subchapter A. Exemptions**

**§304. Radioactive Material Other Than Source Material**

A. – B.1. …

2. Any person who possesses byproduct~~radioactive~~ material received or acquired before September 25, 1971, under the general license, formerly provided in Section B.22, or under a similar general license is exempt from the requirements for a license set forth in this Chapter to the extent that such person possesses, uses, transfers, or owns such byproduct~~radioactive~~ material. This exemption does not apply for radium-226.

3. – 4. …

C. Exempt Items

1. Certain Items Containing Byproduct~~Radioactive~~ Material. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these regulations to the extent that he or she receives, possesses, uses, transfers, owns, or acquires the following products.

a. – a.vii.(c). …

viii. 1 microcurie (0.037 MBq~~37 kBq~~) of radium-226 per timepiece in intact timepieces manufactured~~acquired~~ prior to November 30, 2007~~April 20, 1977~~.

1.b. – 2.b. …

3. Gas and Aerosol Detectors Containing Byproduct~~Radioactive~~ Material

a. Except for persons who manufacture, process, ~~or~~produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct~~radioactive~~ material, any person is exempt from the requirements for a license in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct~~radioactive~~ material in gas and aerosol detectors designed to protect ~~life~~health, safety, or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26, which license authorizes the initial transfer of the product for use under this Section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.~~from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the administrative authority, or any other agreement state, the U.S. Nuclear Regulatory Commission, or any licensing state pursuant to 10 CFR 32.36, or equivalent (e.g., LAC 33:XV.328.C, which authorizes the~~

~~transfer of the detectors to persons who are exempt from regulatory requirements).~~

b. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under LAC 33:XV.304.C.3.a shall apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210.~~Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under LAC 33:XV.304.C.3.a, provided that the device is labeled in accordance with the specific license authorizing distribution of devices to persons generally licensed, and provided further that they meet the requirements of LAC 33:XV.328.C.~~

3.c. – 4.d. …

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**Subchapter C. General Licenses**

**§322. General Licenses: Radioactive Material Other Than Source Material**

A. – A.2. …

B. ~~Reserved.~~Antiquities, Timepieces, and Luminous Devices

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Paragraphs B.1-4 of this Section, radium-226 contained in the following products manufactured prior to November 30, 2007.

a. Antiquities Originally Intended for Use by the General Public. For the purposes of this Paragraph, antiquities are products originally intended for use by the general public and distributed in the late 19$^{th}$ and 20$^{th}$ centuries, (e.g., radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads);

b. intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

c. luminous items installed in air, marine, or land vehicles;

d. all other luminous products, provided that no more than 100 items are used or stored at the same location at any one time; and

e. small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. [For the purposes of this Paragraph, small radium sources are: discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (e.g., cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.]

2. Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued under Paragraph B.1 of this Section are exempt from the provisions of LAC 33:XV.Chapters 3, 4, and 10, and specifically LAC 33:XV.341 and 342 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 this Chapter.

3. Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in Paragraph B.1 of this Section shall:

a. notify the Office of Environmental Compliance within 30 days of possible damage to the product which may result in a loss of the radioactive material, including a brief description of the event and the remedial action taken;

b. not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to LAC 33:XV.499.Appendix D or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by another agreement state or the NRC;

c. not export products containing radium-226, except in accordance with 10 CFR 110;

d. 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. This includes 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 LAC 33:XV.Chapter 3 of these regulations, equivalent regulations of an agreement state, or as approved by the NRC; and

e. respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or the 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 additional time to supply the information by providing the department with a written justification for the request.

4. The general license in Paragraph B.1 of this Section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

C. Reserved.

D. Certain Detecting, Measuring, Gauging, and Controlling Devices

1. A general license is hereby issued to commercial and industrial firms and to research, educational, and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to own, receive, acquire, possess, use, or transfer in accordance with the provisions of Paragraph ~~LAC 33:XV.322.~~D.2 of this Section, byproduct~~radioactive~~ material~~, excluding special nuclear 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.

2. The general license in Paragraph ~~LAC 33:XV.322.~~D.1 of this Section applies only to byproduct~~radioactive~~ material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the administrative authority ~~pursuant to~~in accordance with LAC 33:XV.328.D or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, any other agreement state, or a licensing state that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon that is found in 21 CFR 179.21. The devices shall be received from one of the specific licensees described in this Paragraph or through a transfer made under Subparagraph D.3.h of this Section.

3. Any person who owns, receives, acquires, possesses, uses, or transfers byproduct~~radioactive~~ material in a device pursuant to the general license in Paragraph ~~LAC 33:XV.322.~~D.1 of this Section shall do the following:

a. – b.ii. …

c. assure that the tests required by Subparagraph ~~LAC 33:XV.322.~~D.3.b of this Section and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding, or containment are performed:

i. – ii. …

d. maintain records showing compliance with the requirements of Subparagraphs D.3.b and c of this Section. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation of the radioactive material, its shielding, or containment. Records of tests for leakage of radioactive material required by Subparagraph D.3.b of this Section shall be ~~maintained~~retained for three years after the next required leak test is performed, or until the sealed source is transferred or disposed. Records of tests of the on-off mechanism and indicator required by Subparagraph D.3.b of this Section shall be maintained for ~~one~~three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed. Records required by Subparagraph D.3.c of

this Section shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed;

e. upon the occurrence of 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 0.005 microcurie (185 bequerel) or more of removable radioactive material, immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the administrative authority, the U.S. Nuclear Regulatory Commission, or any other agreement state or licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Office of Environmental Compliance a report containing a brief description of the event and the remedial action taken. In the case of detection of 0.005 microcurie or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use in accordance with LAC 33:XV.332.D shall be submitted to the Office of Environmental Compliance within 30 days of occurrence;

f. ~~do~~shall not abandon the device containing ~~radioactive~~byproduct material;

g. except as provided in Subparagraph D.3.h of this Section, transfer or dispose of the device containing byproduct~~radioactive~~ material only by export as provided in 10 CFR Part 110 or by transfer to a specific licensee of the department, the U.S. Nuclear Regulatory Commission, or any other agreement state or licensing state whose specific license authorizes him or her to receive the device and, within 30 days after transfer of a device to a specific licensee, except when the device is transferred to the specific licensee in order to obtain a replacement device, shall furnish to the Office of Environmental Compliance a report containing:

g.i. – k. …

l. register, in accordance with the provisions in this Subparagraph, 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 megabecquerels (01 millicurie) of radium-226, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described in this Subparagraph, represents a separate general licensee and requires a separate registration and fee:

D.3.l.i. – J.4. …

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**Subchapter D. Specific Licenses**

**§324. Filing Application for Specific Licenses**

A. – C. …

D. An application for a license may include a request for a license authorizing one or more activities.

1. An application from a medical facility, educational institution, or a federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Chapter 7 or the equivalent regulations in 10 CFR 35 of the U. S. Nuclear Regulatory Commission requirements shall include:

a. a request authorizing the production of PET radionuclides, or evidence of an existing license issued under LAC 33:XV.324 or 10 CFR 30 of the U. S. Nuclear Regulatory Commission requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

b. evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in LAC 33:XV.328.J or 10 CFR 32.72(a)(2);

c. identification of the individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in LAC 33:XV.763.K or 10 CFR 32.72(b)(2); and

d. information submitted to members of its consortium for noncommercially transferred PET drugs on the radionuclide; the chemical and physical form; the maximum activity per vial,

syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and the storage of the radioactive drugs by medical use licensees.

2. Except as provided in Paragraphs D.3, 4, and 5 of this Section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source shall:

a. identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210, with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR 32.210; or

b. contain the information identified in 10 CFR 32.210(c).

3. For sources or devices manufactured before October 23, 2012, that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application shall include:

a. all available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

b. sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information shall include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

4. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply the manufacturer, model number, radionuclide, and quantity.

5. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

E. – K. …

[1]These reporting requirements do not supersede or release licensees of complying with requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

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**§328. Special Requirements for Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material**

A. – E.1.b. …

F. Special Requirements for License to Manufacture or Initially Transfer Calibration ~~and~~or Reference Sources Containing Americium-241~~, Plutonium,~~ or Radium-226 for Distribution to Persons Generally Licensed under LAC 33:XV.322.G

1. An application for a specific license to manufacture or initially transfer calibration ~~and~~or reference sources containing americium-241~~, plutonium,~~ or radium-226, for distribution to persons generally licensed under LAC 33:XV.322.G, will be approved subject to the following conditions:

a. …

b. ~~the applicant satisfies the requirements of 10 CFR 32.57, 32.58, 32.59, 32.102, and 70.39 or their equivalent.~~the applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

i. chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

ii. details of construction and design;

iii. details of the method of incorporation and binding of the americium-241or radium-226 in the source;

iv. procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the

americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

v. details of quality control procedures to be followed in the manufacture of the source;

vi. description of labeling to be affixed to the source or the storage container for the source; and

vii any additional information, including experimental studies and test, required by the department to facilitate a determination of the safety of the source.

c. Each source shall contain no more than 5 microcuries of americium-241 or radium-226.

d. The department determines, with respect to any type of source containing more than 0.005 microcurie of americium-241or radium-226, that:

i. the method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

ii. the source has been subjected to and has satisfactorily passed appropriate tests required by Subparagraph F.1.e of this Section.

e. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

i. the initial quantity of radioactive material deposited on each source is measured by direct counting of the source;

ii. the sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion;

iii. the sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in Clause F.1.e.iv of this Section; and

iv. source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

2. Each person licensed to manufacture or initially transfer calibration or reference sources shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

a. the receipt, possession, use, and transfer of this source, Model ____, Serial No. ____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

(Name of Manufacturer or Initial Transferor)

3. Each person licensed to manufacturer or initially transfer calibration or reference sources shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under LAC 33:XV.322.G or equivalent regulations of the U. S. Nuclear Regulatory Commission, licensing state or any other agreement state. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this Paragraph, the source shall be rejected and shall not be transferred to a general licensee under LAC 33:XV.322.G or equivalent regulations of the U. S. Nuclear Regulatory Commission, licensing state, or any other agreement state.

G. Reserved.

H. Licensing the Manufacture and Distribution of ~~Radioactive~~Byproduct Material for Certain In Vitro Clinical or Laboratory Testing under a General License~~.~~

1. An application for a specific license to manufacture or distribute ~~radioactive~~byproduct material for use under an appropriate general license or equivalent will be approved subject to the following conditions:

a. …

b. the ~~radioactive~~byproduct material is to be prepared for distribution in prepackaged units of:

i. iodine-125 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

ii. iodine-131 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

iii. carbon-14 in units not exceeding 0.37 megabequerel (10 microcuries) each;

iv. hydrogen-3 (tritium) in units not exceeding 1.85 megabecuerels (50 microcuries) each;

v. iron-59 in units not exceeding 0.74 megabecquerel (20 microcuries) each;

vi. cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each;

vii. selenium-75 in units not exceeding 0.37 megabecquerel (10 microcuries) each; or

viii. mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each~~.~~; and

c. …

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

ii. displaying the radiation caution symbol described in LAC 33:XV.450.A and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals".

H.1.d. – I.1.b. …

J. Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Byproduct Material for Medical Use under LAC 33:XV.Chapter 7

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized in accordance with LAC 33:XV.Chapter 7 shall be approved if the following conditions are met:

a. – b. …

i. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug~~manufacturer~~ under 21 CFR 207.20(a);

ii. …

iii. licensed as a pharmacy by the Louisiana Board of Pharmacy; ~~or~~

iv. operating as a nuclear pharmacy within a federal medical institution; or

v. a positron emission tomography (PET) drug production facility licensed or registered with a state agency.

1.c. – 2. …

a. may prepare radioactive drugs for *medical use*, as defined in LAC 33:XV.102, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subparagraphs J.2.b and d~~c~~ of this Section, or an individual under the supervision of an authorized nuclear pharmacist as specified in LAC 33:XV.709;

b. – b.ii. …

iii. this individual is designated as an authorized nuclear pharmacist in accordance with Subparagraph J.2.d~~c~~ of this Section;

c. …

d. may designate a *pharmacist* ~~(~~as defined in LAC 33:XV.102~~)~~ as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an *authorized user* on a nuclear pharmacy license issued by the department under these regulations~~;~~ ~~and~~if:

i. the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

ii. the individual practiced at a pharmacy at a government agency or a federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or at an earlier date as recognized by the Nuclear Regulatory Commission;

e. shall provide to the Office of Environmental Compliance:

i. a copy of each individual's certification by the Board Of Pharmaceutical Specialties ~~and~~with the written attestation signed by a preceptor as required by LAC 33:XV.763.K.2;

ii. the department, ~~licensing state,~~ Nuclear Regulatory Commission, or agreement state license~~; or~~

iii. Nuclear Regulatory Commission master materials licensee permit;

iv. the permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

v. documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC; and

vi. a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist, in accordance with Clauses J.2.b.i and iii of this Section.

J.3. – M.4.g. …

[1]Calibration and reference sources licensed under LAC 33:XV.322.G before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2401.B.1.

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**Subchapter Z. Appendices**

**§399. Schedules A and B, and Appendices A, B, C, D, E, F, and G**

Schedule A – Footnotes to Schedule A:

***

NOTE 1. – 4. …

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| **Schedule B<br>Exempt Quantities** | |
|---|---|
| **Byproduct Material** | **Microcuries** |
| ***<br>[See Prior Text in Antimony 122 (Sb 122) – Cerium 144(Ce 144)] | |
| Cesium 129 (Cs 129) | 100 |
| ***<br>[See Prior Text in Cesium 134 (Cs 134) – Chromium 51 (Cr 51)] | |
| Cobalt 57 (Co 57) | 100 |
| ***<br>[See Prior Text in Cobalt 58m (Co 58m) - Gallium 72 (Ga 72)] | |
| Germanium 69 (Ge 69) | 10 |
| ***<br>[See Prior Text in Germanium 71 (Ge 71)] | |
| Gold (Au 195) | 10 |
| ***<br>[See Prior Text in Gold 198 (Au 198) - Hydrogen 3 (H 3)] | |
| Indium 111 (In 111) | 100 |

| Schedule B<br>Exempt Quantities | |
|---|---|
| **Byproduct Material** | **Microcuries** |
| *** | |
| [See Prior Text in Indium 113m (In 113m) - Indium 115 (In 115)] | |
| Iodine 123 (I 123) | 100 |
| *** | |
| [See Prior Text in Iodine 125 (I 125) - Iridium 194 (Ir 194)] | |
| Iron 52 (Fe 52) | 10 |
| *** | |
| [See Prior Text in Iron 55 (Fe 55) - Potassium 42 (K 42)] | |
| Potassium 43 (K 43) | 10 |
| *** | |
| [See Prior Text in Praseodymium 142 (Pr 142) - Rhodium 105 (Rh 105)] | |
| Rubidium 81 (Rb 81) | 100 |
| *** | |
| [See Prior Text in Rubidium 86 (Rb 86) - Silver 111 (Ag 111)] | |
| Sodium 22 (Na 22) | 10 |
| *** | |
| [See Prior Text in Sodium 24 (Na 24) - Ytterbium 175 (Yb 175)] | |
| Yttrium 87 (Y 87) | 10 |
| Yttrium 88 (Y 88) | 10 |
| *** | |
| [See Prior Text in Yttrium 90 (Y 90) - Zirconium 97 (Zr 97)] | |
| Any byproduct material not listed above other than alpha-emitting byproduct material. | 0.1 |

Footnotes to Schedule B – Appendix B; E.4. ...

| Appendix C<br>Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release | | |
|---|---|---|
| **Radioactive Material**[1] | **Release Fraction** | **Quantity (curies)** |
| *** | | |
| [See Prior Text in Actinium-228 - Promethium-147] | | |
| Radium-226 | 0.001 | 100 |

| Appendix C<br>Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release | | |
|---|---|---|
| **Radioactive Material[1]** | **Release Fraction** | **Quantity (curies)** |
| *** | | |
| [See Prior Text in Ruthenium-106 - Packaged waste, alpha[2]] | | |
| Combinations of radioactive materials listed above[1] | | |

[1]For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Appendix E exceeds one.

[2]Waste packaged in Type B containers does not require an emergency plan.

Appendix D. – Appendix G. ...

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## Chapter 4. Standards for Protection against Radiation

## Subchapter H. Waste Disposal

### §460. General Requirements

A. – A.3. …

4. as authorized ~~pursuant to~~in accordance with LAC 33:XV.461, 462, 463, or 464.

B. – B.3. …

4. disposal at a land disposal facility licensed ~~pursuant to~~in accordance with LAC 33:XV.Chapters ~~13~~3, 13, and 14; or

5. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended by the Office of the Secretary, Legal Division, LR 40:289 (February 2014).

**§465. Transfer for Disposal and Manifests**

A. – D. …

E. Any licensee shipping byproduct material as defined in LAC 33:XV.102.*byproduct material*.3, 4, and 5 intended for ultimate disposal at a licensed land disposal facility shall document the information required for the consignee in accordance with the requirements specified in LAC 33:XV.499.Appendix D.

F. Licensed material as defined in LAC 33:XV.102.*byproduct material*.3, 4, and 5 may be disposed of in accordance with LAC 33:XV.Chapter 13, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility licensed under LAC 33:XV.Chapter 13 shall meet the requirements of Subsections A – E of this Section. A licensee may dispose of *byproduct material*, as defined in LAC 33:XV.102.*byproduct material*.3, 4, and 5, at a disposal facility authorized to dispose of such 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.

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**Subchapter Z. Appendices**

**§499. Appendices A, B, C, D, E**

Appendix A – Appendix B, Table III "Releases to Sewers"

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| Tables I, II, and III | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Atomic No. | Radionuclide | Class | Table I Occupational Values | | | Table II Effluent Concentrations | | Table III Releases to Sewers |
| | | | Col. 1 | Col. 2 | Col. 3 | Col. 1 | Col. 2 | Monthly Average |
| | | | Oral | Inhalation | | Air | Water | |

| | | | Ingestion ALI (µCi) | ALI (µCi) | DAC (µCi/ml) | (µCi/ml) | (µCi/ml) | Concentration (µCi/ml) |
|---|---|---|---|---|---|---|---|---|
| *** [See Prior Text Atomic No. 1 Hydrogen -3– Atomic No. 6 Carbon 14] | | | | | | | | |
| 7 | Nitrogen-13[2] | Submersion[1] | - | - | 4E-6 | 2E-8 | - | - |
| 8 | Oxygen-15[2] | Submersion[1] | - | - | 4E-6 | 2E-8 | - | - |
| *** [See Prior Text in Atomic No. 9 Fluorine-18[2] – Atomic No. 101 Mendelevium-258] | | | | | | | | |
| - | Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours | Submersion[1] | - | 2E+2 | 1E-7 | 1E-9 | - | - |
| - | Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours | | - | 2E-1 | 1E-10 | 1E-12 | 1E-8 | 1E-7 |
| - | Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known | - | - | 4E-4 | 2E-13 | 1E-15 | 2E-9 | 2E-8 |

ENDNOTES: 1. – 3. …

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NOTE: 1. – 4. ...

***

Appendix C. – Appendix E. …

A. – C. ...

***

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.
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**Chapter 7. Use of Radionuclides in the Healing Arts**

**§717. Assay of Radiopharmaceutical Dosages**

A. – B.2.a. …

b. a U.S. Nuclear Regulatory Commission or agreement state licensee, for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

c. a PET radioactive drug producer license as specified in LAC 33:XV.324.D, equivalent agreement state requirements or equivalent Nuclear Regulatory Commission requirements.

C. – C.2. …

3. a combination of volumetric measurements and mathematical calculations, based on the measurement made by:

a. a manufacturer or preparer licensed under LAC 33:XV.328.J or equivalent agreement state requirements; or

b. a PET radioactive drug producer licensed under LAC 33:XV.324.D, equivalent agreement state requirements or Nuclear Regulatory Commission requirements.

D. – E.5. …

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**§729. Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies**

A. – B. …

C. The radiopharmaceuticals specified in Subsection A of this Section shall be:

1. obtained from a manufacturer or preparer, or a PET radioactive drug producer, licensed in accordance with LAC 33:XV.328.J, ~~or~~ equivalent Nuclear Regulatory Commission requirements, or agreement state requirements;

2. – 4. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.
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**§731. Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies**

A. – F. …

1. obtained from a manufacturer or preparer, or a PET radioactive drug producer, licensed in accordance with LAC 33:XV.328.K, ~~or~~ equivalent Nuclear Regulatory Commission requirements, or agreement state requirements; or

F.2. – H.1. …

a. obtained from a manufacturer or preparer, or a PET radioactive drug preparer, licensed under LAC 33:XV.328.J, equivalent Nuclear Regulatory Commission requirements, or equivalent agreement state requirements; or

b. – d. …

I. A licensee may use the authorization under LAC 33:XV.328.K, Nuclear Regulatory Commission, or agreement state requirements to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium. This does not relieve the

licensee from complying with applicable FDA, other federal agencies, and agreement state requirements governing radioactive drugs.

J. Each licensee authorized under LAC 33:XV.328.K to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. satisfy the labeling requirements in this Chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

2. possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in this Chapter.

K. A licensee that is a pharmacy authorized under LAC 33:XV.328.K to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual who prepares PET radioactive drugs shall be:

1. an *authorized nuclear pharmacist* as defined in LAC 33:XV.102 and meets the requirements of LAC 33:XV.763.K;

2. a physician who is an *authorized user* as defined in LAC 33:XV.102 and meets the requirements specified in LAC 33:XV.763.D or E; or

3. an individual who was trained under the supervision of an *authorized user* or an *authorized nuclear pharmacist* as specified in LAC 33:XV.709.A or B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.

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**§732. Permissible Molybdenum-99 Concentration**

A. A licensee shall not administer to humans a radiopharmaceutical containing:

1. more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m)~~.~~;

2. more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or

3. more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

B. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall measure the molybdenum-99 concentration or the rubidium-82 concentration in each eluate or extract.

C. A licensee who must measure molybdenum concentration shall retain a record of each measurement for ~~two~~three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

D. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.
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**§735. Use of Radiopharmaceuticals for Therapy**

A. – B. …

1. obtained from a manufacturer, ~~or~~ preparer, or a PET radioactive drug producer, licensed in accordance with LAC 33:XV.328.J or equivalent Nuclear Regulatory Commission or agreement state requirements; or

B.2. – C.4. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq. and 2104.B.1.
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**Chapter 13. Licensing Requirements for Land Disposal of Radioactive Waste**

**Subchapter A. General Provisions**

**§1302. Definitions**

A. As used in this Chapter, the following definitions apply.

***

*Waste*—those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, that is radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Section 11.e (2) of the Atomic Energy Act (uranium or thorium tailings and waste) and LAC 33:XV.102.*byproduct material*.

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