

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.

Authorized Nuclear Pharmacist—a pharmacist who:

1. ...
2. is identified as an authorized nuclear pharmacist on a departmental, licensing state, Nuclear Regulatory Commission, or agreement state specific license that authorizes ~~the use of radioactive material in~~medical use or the practice of nuclear pharmacy; or
3. is identified as an authorized nuclear pharmacist on a permit issued by the department, licensing state, Nuclear Regulatory Commission, or agreement state specific licensee of broad scope authorized to permit the use of radioactive material inmedical use license that authorizes medical use or the practice of nuclear pharmacy; or
4. is identified as an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; or
5. is identified as an authorized nuclear pharmacist on a permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
6. is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

7. is designated an an authorized nuclear pharmacist in accordance with LAC 33:XV.328.J.2.d.

48. meets the requirements specified in LAC 33:XV.763.K and M.

Byproduct Material—

1. – 4. ...

5. any discrete source of naturally occurring radioactive material, other than source material that the U. S. Nuclear Regulatory Ceommission, 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.

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*, Paragraphs 3, 4, and 5 of this Section; and

2. ...

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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), LR 40:1338 (July 2014), LR 40:1926 (October 2014), LR 41:**.

Chapter 3. Licensing of ByproductRadioactive Material

§301. Purpose and Scope

A. This Chapter and Chapters 7, 13, and 15 provide for the licensing of radioactive material. No person shall manufacture, produce, receive, possess, use, transfer, own, or acquire byproductradioactive material except as authorized in a specific or general license issued pursuant to this Chapter or as otherwise provided in these regulations.

B. ...

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, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of the Secretary, Legal Division, LR 41:**.

Subchapter A. Exemptions

§304. Radioactive Material Other Than Source Material

A. – C.4.d. ...

5. Certain Industrial Devices.

a. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct 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 for a license set forth in these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these

certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under this Section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

b. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under Subparagraph a of this section, should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with LAC 33:XV.361.

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Subchapter C. General Licenses

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

A. ~~Reserved. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment that have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR 31.3. Attention is directed particularly to the provisions of 10 CFR 20 concerning labeling of containers. This general license is subject to the provisions of LAC 33:XV.104-109, 304.A.3 and 4, 331, 340, 350, and Chapters 4, 10, and 15 of these regulations.~~

~~1. Static Elimination Devices. This includes devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device.~~

~~2. Ion-Generating Tubes. This includes devices designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.~~

B.1. – 3.a. ...

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.465.F99, 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;

B.3.c. – D.3.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 (0.1 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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(October 2005), LR 32:811 (May 2006), LR 33:448 (March 2007), LR 33:2177 (October 2007), amended by the Office of the Secretary, Legal Division, LR 40:284 (February 2014), LR 41:**.

Subchapter D. Specific Licenses

§324. Filing Application for Specific License

A. – D.1.c. ...

d. information on the PET drugs to be submitted to members of its consortium for noncommercially transferred to members of its consortium, including 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.

D.2. – K. ...

¹These 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 Byproduct Material

A. – D.1.e ...

f. the device has been registered in the Sealed Source and Device Registry.

2. – 4.g. ...

E. Special Requirements for the Manufacture, Assembly, ~~or Repair~~, or Initial Transfer of

Luminous Safety Devices for Use in Aircraft

1. An application for a specific license to manufacture, assemble, ~~or repair~~, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under LAC 33:XV.322.E, will be approved subject to the following conditions:

a. ...

b. the applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55, and 32.56, ~~and 32.101~~ or their equivalent.

F. – I.1.a. ...

b. the criteria of 10 CFR 32.61; and 32.62; ~~and 32.103~~ are met.

J. – J.2.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 if:~~

J.2.d.i. – L.1.c. ...

d. the source or device has been registered in the Sealed Source and Device

Registry.

L.2. – M.4.g. ...

¹Calibration 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.

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§361. Registration of Product Information

A. Any manufacturer or initial distributor of a sealed source or a device containing a sealed source whose product is intended for use under a specific license may submit a request to the department for evaluation of radiation safety information about its product and for its registration.

B. – C. ...

D. The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. LAC 33:XV.Chapter 3 includes: specific criteria that apply to certain exempt products; specific criteria applicable to certain generally licensed devices; and specific provisions that apply to certain specifically licensed items.

E. After completion of the evaluation, the department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

F. ...

G. Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

1. calibration and reference sources containing no more than:

a. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

b. 0.37 MBq (10 μ Ci), for alpha emitting radionuclides; or

2. the intended recipients are qualified by training and experience and have sufficient

facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are

qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

a. the intended recipients are licensed under LAC 33:XV.Chapter 3 or comparable provisions of the U. S. Nuclear Regulatory Commission or an agreement state; or

b. the recipients are authorized for research and development; or

c. the sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

H. After the certificate is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this Section. The department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

I. Inactivation of Certificates of Registration of Sealed Sources and Devices.

1. A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the department shall request inactivation of the registration certificate. Such a request must be made to the Office of Environmental Compliance and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

2. If a distribution license is to be terminated in accordance with LAC 33:XV.332, the licensee shall request inactivation of its registration certificates associated with that distribution license

before the department will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

3. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

GJ. Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

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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. ...

Schedule B Exempt Quantities	
Byproduct Material	Microcuries
*** [See Prior Text in Antimony 122 (Sb 122) – Gallium 72 (Ga 72)]	
Germanium 698 (Ge 698)	10
*** [See Prior Text in Germanium 71 (Ge 71) – Zirconium 97 (Zr 97)]	

Schedule B Exempt Quantities	
Byproduct Material	Microcuries
Any byproduct material not listed above other than alpha-emitting byproduct material.	0.1

Footnotes to Schedule B – 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 in accordance with LAC 33:XV.461, 462, 463, 464, or 4645.F.

B. – B.5. ...

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

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§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 and transfer this recorded manifest information to the intended 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 or transferred for ultimate disposal 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”

List of Elements - Atomic Numbers		
Name	Symbol	Number
*** [See Prior Text in Actinium Ac 89 – Niobium Nb 41]		
<u>Nitrogen</u>	<u>N</u>	<u>7</u>
Osmium	Os	76
<u>Oxygen</u>	<u>O</u>	<u>8</u>
*** [See Prior Text in Palladium Pd 46 – Zirconium Zr 40]		

Tables I, II, and III. ...

ENDNOTES: 1. – 3. ...

NOTE: 1. – 4. ...

Appendix C. – Appendix E. ...

A. – C. ...

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Chapter 5. Radiation Safety Requirements for Industrial Radiographic Operations

Subchapter A. Equipment Control

§541. Locking of Sources of Radiation

A. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked, with the key removed at all times for a keyed-lock, when not under the direct surveillance of a radiographer or a radiographer trainee except at permanent radiographic installations in accordance with LAC 33:XV.585. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

B. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked, with the key removed at all times for a keyed-lock, when containing sealed sources, except when under the direct surveillance of a radiographer or radiographer trainee.

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Chapter 7. Use of Radionuclides in the Healing Arts

§731. Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization

Studies

A. – H.1.d. ...

I. A licensee may use the authorization under LAC 33:XV.328-~~K4.D.1~~, 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-~~K4.D.1~~ to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. – 2. ...

K. A licensee that is a pharmacy authorized under LAC 33:XV.328-~~K4.D.1~~ 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; or

~~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.~~

L. A pharmacy that is authorized under LAC 33:XV.324.D.1 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of LAC 33:XV.328.J.2.e.

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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*, Paragraphs 3, 4, and 5.

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