NOTICE OF INTENT

Department of Environmental Quality

Office of the Secretary

Legal Affairs and Criminal Investigations Division

Medical Use of Byproduct Material

(LAC 33:XV.102, 328, 331, 613, 706, 708, 710, 712, 718, 719, 732, 735, 739, 741, 742, 743, 744, 745, 747, 750, 762, 763, 777, 915, 1510, and 1520) (RP069ft)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.102, 328, 331, 613, 706, 708, 710, 712, 718, 719, 732, 735, 739, 741, 742, 743, 744, 745, 747, 750, 762, 763, 777, 915, 1510, and 1520 (Log #RP069ft).

This Rule is identical to federal regulations found in 10 CFR 30, 32, and 35, which are applicable in Louisiana. For more information regarding the federal requirement, contact Deidra Johnson at (225) 219-3985. No fiscal or economic impact will result from the Rule. This Rule will be promulgated in accordance with the procedures in R.S. 49:953(F)(3) and (4).

This Rule updates the regulations pertaining to the medical use of byproduct material. This Rule was promulgated by the Nuclear Regulatory Commission (NRC) as RATS IDs 2018-1 and 2020-2. This Rule will update the state regulations to be compatible with changes in the federal regulations. The changes in the state regulations are category B, C, and H&S requirements for the state of Louisiana to remain an NRC agreement state. The basis and rationale for this Rule are to mirror the federal regulations and maintain an adequate agreement state program. This Rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 1. General Provisions

§102. Definitions and Abbreviations

A. 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.

\* \* \*

*Associate Radiation Safety Officer*—an individual who:

a. meets the requirements in LAC 33:XV.763.A and M; and

b. is currently identified as an associate radiation safety officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the radiation safety officer on:

i. a specific medical use license issued by the NRC or an agreement state; or

ii. a medical use permit issued by a NRC master material licensee.

\* \* \*

*Ophthalmic Physicist*—an individual who:

a. meets the requirements in LAC 33:XV.719.N.1.b and 763.M; and

b. is identified as an ophthalmic physicist on a:

i. specific medical use license issued by the NRC or an agreement state;

ii. permit issued by a NRC or agreement state broad scope medical use licensee;

iii. medical use permit issued by a NRC master material licensee; or

iv. permit issued by a NRC master material licensee broad scope medical use permittee.

\* \* \*

*Preceptor*―an individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a radiation safety officer, or an associate radiation safety officer.

\* \* \*

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

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), LR 40:1338 (July 2014), LR 40:1926 (October 2014), LR 41:1276 (July 2015), LR 41:2321 (November 2015), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 44:2137 (December 2018), LR 45:1752 (December 2019), LR 47:

**Chapter 3. Licensing of Byproduct Material**

**Subchapter D.** **Specific Licenses**

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

A. — J.1.b.v. …

c. the applicant submits to the Office of Environmental Compliance information 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 storage of the radioactive drugs by medical use licensees; and

d. the applicant commits to the following labeling requirements:

i. the label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "caution, radioactive material" or "danger, radioactive material," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

ii. a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "caution, radioactive material" or "danger, radioactive material" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. — 2.e. …

i. a copy of each individual's certification by a specialty board whose certification process has been recognized by the department, the NRC, or agreement state as specified in LAC 33:XV.763.K;

2.e.ii. — 3.b. …

4. A licensee shall satisfy the labeling requirements in Subparagraph J.1.d. of this Section.

5. Nothing in this Section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

K. — M.4.g. …

\* \* \*

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

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), LR 24:2092 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2569 (November 2000), LR 26:2768 (December 2000), LR 27:1228 (August 2001), LR 30:1664 (August 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2526 (October 2005), LR 33:2179 (October 2007), LR 36:1771 (August 2010), amended by the Office of the Secretary, Legal Division, LR 38:2746 (November 2012), LR 40:286 (February 2014), LR 40:1341 (July 2014), LR 41:1278 (July 2015), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 44:2137 (December 2018), LR 47:

**§331. Specific Terms and Conditions of Licenses**

A. …

B. No license issued or granted in accordance with these regulations and no right to possess or utilize radioactive material granted by any license issued pursuant to this Chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of the act and shall give its consent in writing.

1. …

C. Each person licensed by the administrative authority in accordance with these regulations shall confine his use and possession of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued in accordance with these regulations shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Chapter 15.

D. — F. …

G. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall:

1. test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with LAC 33:XV.732;

2. record the results of each test and retain each record for three years after the record is made; and

3. report the results of any test that exceeds the permissible concentration listed in LAC 33:XV.732.A at the time of generator elution, in accordance with LAC 33:XV.732.D and E.

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

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 Environmental Assessment, Environmental Planning Division, LR 26:2571 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2527 (October 2005), LR 33:2180 (October 2007), amended by the Office of the Secretary, Legal Division, LR 40:1928 (October 2014), LR 41:2132 (October 2015), LR 47:

**Chapter 6.** **X-Rays in the Healing Arts**

**§613. Notifications, Reports, and Records of Medical Events**

A. — C.

D. All reports, notifications, and records shall be in accordance with LAC 33:XV.712.D, E, and G.

E. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, LR 31:1064 (May 2005), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 45:751 (June 2019), LR 45:1758 (December 2019), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

**Chapter 7. Use of Radionuclides in the Healing Arts**

**§706. Radiation Safety Officer**

A. A licensee’s management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, shall assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

B. — 4. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2588 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 32:813 (May 2006), LR 47:

§708. Statement of Authorities and Responsibilities

A. A licensee shall provide sufficient authority, organizational freedom, time, resources, and management prerogative to the radiation safety officer and the radiation safety committee to:

1. …

2. initiate, recommend, or provide corrective actions;

3. stop unsafe operations; and

4. verify implementation of corrective actions.

B. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§710. Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

A. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that:

B.1. — F.1.a. …

b. the identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

F.2. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 30:1174 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 33:2185 (October 2007), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§712. Notifications, Reports, and Records of Medical Events

A. A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:

1. a dose that differs from the prescribed dose, or the dose that would have resulted from the prescribed dosage, by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin, and:

1.a. — 2. …

a. an administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

b. an administration of a radioactive drug containing byproduct material by the wrong route of administration;

c. — e. …

3. a dose to the skin or an organ or tissue other than the treatment site that exceeds by:

a. 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

b. 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

B. For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

1. the total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

2. the total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

3. an administration that includes any of the following:

a. the wrong radionuclide;

b. the wrong individual or human research subject;

c. sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

d. a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

C. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

D. The following notifications are required for a medical event.

1. The licensee shall notify the Office of Environmental Compliance by telephone at (225) 765-0160 in the manner provided in LAC 33:I.3923 no later than the next calendar day after discovery of the medical event.

2. The licensee shall submit a written report to the Office of Environmental Compliance using the procedures provided in LAC 33:I.3925.B and C within 15 days after discovery of the medical event.

a. The written report shall include:

i. the licensee's name;

ii. the name of the prescribing physician;

iii. a brief description of the event;

iv. why the event occurred;

v. the effect, if any, on the individual(s) who received the administration;

vi. what actions, if any, have been taken or are planned to prevent recurrence; and

vii. certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. The report may not contain the individual's name or any other information that could lead to identification of the individual.

3. The licensee shall notify the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this Paragraph, the notification to the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

E. Each licensee shall retain a record of each medical event for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual affected by the medical event, and the individual's referring physician), the individual's driver's license or state identification number and the issuing state, a brief description of the medical event, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

F. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, the individual, or the individual's responsible relatives or guardians.

G. A licensee shall:

1. annotate a copy of the report provided to the department with:

a. the name of the individual who is the subject of the event; and

b. the identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

2. provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2102 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2588 (November 2000), LR 30:1174 (June 2004), LR 30:1679 (August 2004), amended by the Office of Environmental Assessment, LR 30:2804 (December 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§718. Authorization for Calibration, Transmission, and Reference Sources

A. Any person authorized by LAC 33:XV.702 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, transmission, and reference use:

1. sealed sources manufactured and distributed by persons specifically licensed in accordance with Chapter 3 of these regulations or equivalent provisions of the U.S. NRC, an agreement state, or a licensing state, and that do not exceed 30 millicuries (1.11 GBq) each;

2. sealed sources redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under LAC 33:XV.328.L or equivalent agreement state regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions and do not exceed 30 mCi (1.11 GBq) each;

3. any byproduct material with a half-life of 120 days or less in individual amounts not to exceed 15 millicuries (0.56 GBq);

4. any byproduct material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (7.4 MBq) or 1000 times the quantities in LAC 33:XV.499.Appendix C; or

5. technetium-99m in amounts as needed.

B. Byproduct material in sealed sources authorized by this provision shall not be:

1. used for *medical use* as defined in LAC 33:XV.102 except in accordance with the requirements in LAC 33:XV.739; or

2. combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this Section.

C. A licensee using calibration, transmission, and reference sources in accordance with the requirements in Subsections A or B of this Section need not list these sources on a specific medical use license.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§719. Requirements for Possession of Sealed Sources and Brachytherapy Sources

A. — K. …

L. A licensee shall mathematically correct the outputs or activities determined in Subsection J of this Section for physical decay at intervals consistent with 1 percent physical decay.

M. …

N. Strontium-90 Sources for Ophthalmic Treatments.

1. Licensees who use strontium-90 for ophthalmic treatments shall ensure that certain activities as specified in Paragraph N.2 of this Section are performed by either:

a. an authorized medical physicist; or

b. an individual who:

i. is identified as an ophthalmic physicist on a specific medical use license issued by the NRC or an agreement state; permit issued by an NRC or agreement state broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material licensee broad scope medical use permittee;

ii. holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university;

iii. has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

iv. has documented training in:

(a). the creation, modification, and completion of written directives;

(b). procedures for administrations requiring a written directive; and

(c). performing the calibration measurements of brachytherapy sources as detailed in LAC 33:XV.719.J.

2. The individuals who are identified in Paragraph N.1 of this Section shall:

a. calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under LAC 33:XV.719.J; and

b. assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures shall:

i. include the frequencies that the individual meeting the requirements in Paragraph N.1 of this Section will observe treatments;

ii. review the treatment methodology;

iii. calculate treatment time for the prescribed dose; and

iv. review records to verify that the administrations were in accordance with the written directives.

3. Licensees shall retain a record of the activity of each strontium-90 source for the life of the source in accordance with LAC 33:XV.744.C.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), LR 30:1176 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2533 (October 2005), LR 33:2185 (October 2007), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§732. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

A. — C. …

D. The licensee shall notify the Office of Environmental Compliance by telephone at (225) 765-0160 and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration specified in LAC 33:XV.732.A at the time of generator elution. The telephone report to the department shall include:

1. the manufacturer;

2. model number, and serial number (or lot number) of the generator;

3. the results of the measurement;

4. the date of the measurement;

5. whether dosages were administered to patients or human research subjects;

6. when the distributor was notified; and

7. the action taken.

E. By an appropriate method listed in LAC 33:I.3923, the licensee shall submit a written report to the Office of Environmental Compliance within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution.

1. The written report shall include:

a. the action taken by the licensee;

b. the patient dose assessment;

c. the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects;

d. the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and

e. the information in the telephone report as required by Subsection D of this Section.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2589 (November 2000), amended by the Office of the Secretary, Legal Division, LR 40:291 (February 2014), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§735. Use of Radiopharmaceuticals for Therapy

A. B.2. …

C. A licensee may use any unsealed byproduct material identified in 763.E.1.b.i.(b).(vii) prepared for medical use and for which a written directive is required that is:

1. obtained from:

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 in accordance with LAC 33:XV.324.D.1 or equivalent NRC or agreement state requirements; or

2. excluding production of PET radionuclides, prepared by:

a. an authorized nuclear pharmacist;

b. a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.D or E.1; or

c. an individual under the supervision, as specified in LAC 33:XV.709, of the authorized nuclear pharmacist in Subparagraph C.2.a of this Section or the physician who is an authorized user in Subparagraph C.2.b of this Section; or

3. obtained from and prepared by a NRC or agreement state licensee, for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

4. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2104 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Division, LR 40:292 (February 2014), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§739. Use of Sealed Sources and Medical Devices for Diagnosis

A. A licensee shall use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

B. A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of LAC 33:XV.713.A.1 are met.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§741. Use of Sources for Brachytherapy

A. — B. …

1. as approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but shall be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. in research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, provided the requirements of LAC 33:XV.713.A.1 are met.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1178 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:813 (May 2006), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§742. Safety Instructions

A. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving brachytherapy and cannot be released under LAC 33:XV.725. Refresher training shall be provided at intervals not to exceed one year.

B. — B.4.a. …

b. visitation authorized in accordance with LAC 33:XV.421.F;

5. — 6. …

C. A licensee shall maintain a record of individuals receiving instruction required by Subsection A of this Section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1179 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:813 (May 2006), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§743. Safety Precautions

A. — B. …

1. dislodged from the patient; and

B.2. C. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2105 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1179 (June 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 32:814 (May 2006), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§744. Brachytherapy Records

A. — A.1. …

2. As soon as possible after removing sources from a patient or a human research subject, the licensee shall return brachytherapy sources to an area of storage from the area of use, and immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

3. A licensee shall maintain a record of brachytherapy source accountability required by Paragraphs 1 and 2 of this Section for three years.

a. For temporary implants, the record shall include:

i. the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

ii. the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

b. For permanent implants, the record shall include:

i. the number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

ii. the number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

iii. the number and activity of sources permanently implanted in the patient or human research subject.

B. — C.2.b. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1179 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§745. Surveys After Source Implant and Removal

A. …

B. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. …

D. A licensee shall maintain a record of patient or human research subject surveys that demonstrates compliance with Subsections A, B, and C of this Section for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1180 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§747. Use of Sealed Sources in Teletherapy Units, Remote Afterloader Units, and Gamma Stereotactic Radiosurgery Units

A. — A.2. …

B. A licensee shall use teletherapy units, photon-emitting remote afterloader units, or gamma stereotactic radiosurgery units:

1. approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of LAC 33:XV.713.A.1 are met.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1180 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§750. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

A. — C.2. …

D. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall:

1. ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training shall be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training; and

2. provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties. The instructions shall include instructions in:

a. the procedures identified in Paragraph A.4 of this Section; and

b. the operating procedures for the unit.

E. …

F. A licensee shall maintain a record of individuals receiving instruction required by Subsection D of this Section, a description of the instruction, the date of instruction, the name(s) of the attendee(s), and the name of the individual who gave the instruction for three years.

G. A licensee shall retain a copy of the procedures required by Paragraphs A.4 and D.2 of this Section until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 30:1180 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

§762. Full Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism and other safety components.

B. — C. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:1186 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

**§763. Training**

A. Training for a Radiation Safety Officer and Associate Radiation Safety Officer. Except as provided in Subsection B of this Section, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer as provided in LAC 33:XV.706 to be an individual:

1. who is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in Paragraph A.4 of this Section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. — b. …

i. hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

ii. — ii.(a). …

(b). in clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Subsection B or D, or Paragraph E.1 of this Section; and

1.b.iii. — 2.a.v. …

b. one year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a NRC or agreement state license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of byproduct material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a NRC or an agreement state license or permit issued by a NRC master material licensee. The full-time radiation safety experience shall involve the following:

i. — vi. …

vii. disposing of byproduct material; and

c. this individual shall obtain a written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation shall state that the individual has satisfactorily completed the requirements in Paragraphs A.2 and A.4 of this Section, and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

3. …

a. is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state in accordance with Subsection J of this Section, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee is seeking the approval of the individual as radiation safety officer or an associate radiation safety officer, and who meets the requirements in Paragraph A.4 of this Section; or

b. is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a NRC or an agreement state license, or a permit issued by a NRC or an agreement state licensee of broad scope, or a permit issued by the NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer, and meets the requirements in Paragraph 4 of this Section; or

c. has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a NRC master material license. The individual shall also meet the requirements in Paragraph A.4 of this Section.

4. The individual shall have training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, an associate radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

B. …

1. An individual identified on an agreement state or a NRC license or a permit issued by a NRC or an agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist, or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of Subsections A, J, or K of this Section, respectively, except the radiation safety officers and authorized medical physicists identified in this Paragraph shall meet the training requirements in Paragraphs A.4 or J.3 of this Section as appropriate, for any material or uses for which they were not authorized prior to this date.

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of Subsection A of this Section to be identified as a radiation safety officer or as an associate radiation safety officer on a NRC or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Subsection J of this Section, for those materials and uses that these individuals performed on or before October 24, 2005.

4. A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a government agency or federally-recognized Indian tribe before November 30, 2007, or at any other location of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of Subsections A, J, or K of this Section, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this Paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this Chapter.

5. Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the NRC or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or an agreement state broad scope licensee, or a permit issued by a commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of this Chapter.

6. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the NRC or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or an agreement state broad scope licensee, or a permit issued by a NRC master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of this Chapter for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

a. for uses authorized under LAC 33:XV.729 or 731, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

b. for uses authorized under LAC 33:XV.735.C, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

c. for uses authorized under LAC 33:XV.741, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

d. for uses authorized under LAC 33:XV.739, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

7. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed 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 an earlier date as noticed by the NRC, need not comply with the training requirements of this Chapter when performing the same medical uses. A physician, dentist, or podiatrist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this Paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this Chapter.

8. Individuals who need not comply with training requirements as described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorizations on Agreement State or NRC licenses for the same uses for which these individuals are authorized.

C. …

1. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensees Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in Clauses C.3.a.i-ii of this Section; and

b. …

2. who is an authorized user under Subsection D or Paragraph E.1 of this Section, or equivalent agreement state requirements, or NRC requirements; or

3. …

a. has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience shall include:

i. — ii.(f). …

b. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraph C.3.a of this Section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized in LAC 33:XV.729. The attestation shall be obtained from either:

i. a preceptor authorized user who meets the requirements in Subsections B, C, D, or Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements; or

ii. a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Subsections B, C, D, or Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Subparagraph C.3.a of this Section.

D. …

1. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1.a. — 3. …

a. has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience shall include, at a minimum:

i. — i.(e). …

ii. work experience, under the supervision of an authorized user, who meets the requirements in this Subsection, Subsection B, or Subclause D.3.a.ii.(g) and Paragraph E.1 of this Section, or equivalent agreement state requirements, or NRC requirements. An authorized nuclear pharmacist who meets the requirements in Subsections B or K of this Section may provide the supervised work experience for Subclause D.3.a.ii.(g) of this Section. Work experience shall involve:

(a). — (g). …

b. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraph D.3.a of this Section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized in LAC 33:XV.729 and LAC 33:XV.731.H. The attestation shall be obtained from either:

i. a preceptor authorized user who meets the requirements in this Subsection, Subsection B, or Paragraph E.1 and Subclause D.3.a.ii.(g) of this Section, NRC or equivalent agreement state requirements; or

ii. a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Subsection, Subsection B, or Paragraph E.1 and Subclause D.3.a.ii.(g), or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Subparagraph D.3.a of this Section.

E. — E.1. …

a. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in Division E.1.b.i.(b).(vii) of this Section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:

i. successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs shall include 700 hours of training and experience as described in Subclause E.1.b.i.(a) through Division E.1.b.i.(b).(v) of this Section. Eligible training programs shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

a.ii. – b. …

i. has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience shall include:

(a). — (a).(v). …

(b). work experience, under the supervision of an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, or equivalent agreement state requirements or NRC requirements. A supervising authorized user, who meets the requirements in Subparagraph E.1.b of this Section, shall also have experience in administering dosages in the same dosage category or categories (i.e., Division E.1.b.i.(b).(vii) of this Section) as the individual requesting authorized user status. The work experience shall involve:

(i). — (vi). …

(vii). administering dosages of radioactive drugs to patients or human research subjects from the three categories in this Division. Radioactive drugs containing radionuclides in categories not included in this Division are regulated elsewhere in this Chapter. This work experience shall involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

[a]. — [b]. …

[c]. parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

ii. has obtained written attestation that the individual has satisfactorily completed the requirements in Clause E.1.b.i of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized in LAC 33:XV.735.C for which the individual is requesting authorized user status. The attestation shall be obtained from either:

(a). a preceptor authorized user who meets the requirements in this Paragraph, Subsection B of this Section, equivalent agreement state requirements, or NRC requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(b). a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, equivalent agreement state requirements, or NRC requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Clause E.1.b.i of this Section.

2. …

a. who is certified by a medical specialty board whose certification process includes all of the requirements in Clauses E.2.c.i and ii of this Section and whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. — c. …

i. has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

(a). — (e). …

ii. has work experience, under the supervision of an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, or Paragraphs E.1 or E.3 of this Section, or equivalent agreement state requirements or NRC requirements. A supervising authorized user who meets the requirements in Subparagraph E.1.b of this Section shall also have experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[a] or [b] of this Section. The work experience shall involve:

(a). — (f). …

iii. has obtained written attestation that the individual has satisfactorily completed the requirements in Clauses E.2.c.i and ii of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized in LAC 33:XV.735.C. The attestation shall be obtained from either:

(a). a preceptor authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraphs E.1 or E.3 of this Section, equivalent NRC or agreement state requirements, and has experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[a] or [b] of this Section; or

(b). a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraphs E.1 or E.3 of this Section, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[a] or [b] of this Section, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Clauses E.2.c.i and ii of this Section.

3. …

a. who is certified by a medical specialty board whose certification process includes all of the requirements in Clauses E.3.c.i and ii of this Section, and whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. — c. …

i. has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training shall include:

(a). — (e). …

ii. has work experience, under the supervision of an authorized user who meets the requirements in this Paragraph of this Section, Subsection B of this Section, Paragraph E.1 of this Section, or equivalent agreement state requirements or NRC requirements. A supervising authorized user who meets the requirements in Subparagraph E.1.b of this Section shall also have experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[b] of this Section. The work experience shall involve:

(a). — (f). …

iii. has obtained written attestation that the individual has satisfactorily completed the requirements in Clauses E.3.c.i and ii of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized in LAC 33:XV.735.C. The attestation shall be obtained from either:

(a). a preceptor authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraphs E.1 of this Section, equivalent NRC or agreement state requirements, and has experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[b] of this Section; or

(b). a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraphs E.1 of this Section, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in Subdivision E.1.b.i.(b).(vii).[b] of this Section, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Clauses E.3.c.i and ii of this Section.

4. …

a. who is an authorized user in accordance with Paragraph E.1 of this Section for uses listed in Subdivision E.1.b.i.(b).(vii).[c] of this Section, or equivalent agreement state requirements or NRC requirements; or

b. who is an authorized user in accordance with Subsections F or I of this Section, or equivalent agreement state requirements, NRC requirements, and who meets the requirements in Subparagraph E.4.d of this Section; or

c. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state in accordance with Subsections F or I of this Section, and who meets the requirements in Subparagraph E.4.d of this Section; or

d. …

i. has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in Subdivision E.1.b.i.(b).(vii).[c]. The training shall include:

(a). — (e). …

ii. has work experience, under the supervision of an authorized user who meets the requirements in this Paragraph, Subsection B, or Paragraph E.1 of this Section, or equivalent agreement state requirements, or NRC requirements in the parenteral administration listed in Subdivision E.1.b.i.(b).(vii).[c]. A supervising authorized user who meets the requirements in this Paragraph, Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience shall involve:

(a). — (e). …

(f). administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in Subdivision E.1.b.i.(b).(vii).[c]; and

iii. has obtained written attestation that the individual has satisfactorily completed the requirements in Clauses E.4.d.i and ii of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation shall be obtained from either:

(a). a preceptor authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in this Paragraph, Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements, shall have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(b). a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Paragraph, Subsection B of this Section, Paragraph E.1 of this Section, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Clauses 4.d.i and ii of this Section.

F. Training for Use of Manual Brachytherapy Sources. Except as provided in Subsection B of this Section, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized in LAC 33:XV.741.B to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

1.b. — 2.a.i.(d).

ii. 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Subsection, Subsection B of this Section or equivalent agreement state requirements or NRC requirements at a medical facility authorized to use byproduct materials in accordance with LAC 33:XV.741.B, involving:

(a). — (f). …

b. has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in this Subsection, Subsection B of this Section or equivalent agreement state requirements, or NRC requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Subparagraph F.2.a.ii of this Section; and

c. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraphs F.2.a and b of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized in LAC 33:XV.741.B. The attestation shall be obtained from either:

i. a preceptor authorized user who meets the requirements in this Subsection, Subsection B of this Section, or equivalent NRC or agreement state requirements; or

ii. a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Subsection, Subsection B of this Section or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Subparagraphs 2.a and b of this Section.

G. — G.2. …

a. has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

i. — iv. …

b. supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

i. — iv. …

c. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Subsections B or F and G of this Section, or equivalent agreement state requirements, or NRC requirements that the individual has satisfactorily completed the requirements in Subparagraphs G.2.a and b of this Section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

H. Training for Use of Sealed Sources and Medical Devices for Diagnosis. Except as provided in Subsection B of this Section, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized in LAC 33:XV.739 to be a physician, dentist, or podiatrist:

1. who is certified by a specialty board whose certification process includes all of the requirements in Paragraphs H.3 and 4 of this Section and whose certification has been recognized by the NRC or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state will be posted on the NRC's Medical Uses Licensee Toolkit web page; or

2. who is an authorized user for uses listed in LAC 33:XV.731.H, or equivalent NRC or agreement state requirements; or

3. who has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:

a. radiation physics and instrumentation;

b. radiation protection;

c. mathematics pertaining to the use and measurement of radioactivity; and

d. radiation biology; and

4. who has completed training in the use of the device for the uses requested.

I. …

1. who is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in Paragraph I.3 of this Section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

1.b. — 2.a.i.(d). …

ii. 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Subsection, or Subsection B of this Section or equivalent agreement state requirements or NRC requirements at a medical facility that is authorized to use byproduct materials in LAC 33:XV.747 involving:

(a). — (f). …

b. has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in this Subsection, or Subsection B of this Section or equivalent agreement state requirements, or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Clause I.2.a.ii of this Section; and

c. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraphs I.2.a and b and Paragraph I.3 of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation shall be obtained from either:

i. a preceptor authorized user who meets the requirements in this Subsection or Subsection B of this Section or equivalent agreement state requirements or NRC requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

ii. a residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Subsection, Subsection B of this Section, or equivalent NRC or agreement state requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program shall be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and shall include training and experience specified in Subparagraphs 2.a and b of this Section.

3. who has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

J. …

1. who is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in Paragraph J.3 of this Section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

b. …

i. under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this Section by the NRC or an agreement state; or

ii. in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for an authorized user in Subsection B, F or I of this Section; and

1.c. — 2. …

a. holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services, and shall include:

i. — iv. …

b. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraph J.2.a and Paragraph J.3 of this Section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in this Subsection, Subsection B of this Section or equivalent agreement state requirements or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

3. who has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

K. …

1. who is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in Subparagraph K. 2.b of this Section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1.a. — 2.a.ii.(e). …

b. has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in Subparagraph K.2.a, of this Section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

L. — M. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:2106 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2590 (November 2000), LR 30:1186 (June 2004), amended by the Office of Environmental Assessment, LR 31:1061 (May 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 32:814 (May 2006), LR 34:983 (June 2008), LR 34:2121 (October 2008), LR 36:1772 (August 2010), amended by the Office of the Secretary, Legal Division, LR 38:2748 (November 2012), LR 40:1342 (July 2014), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 44:2138 (December 2018), LR 45:1179 (September 2019), LR 47:

**§777. Written Directives**

A. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. — B.1. …

2. for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131:

2.a. — 5.d. …

e. the total dose;

6. for permanent implant brachytherapy:

a. before implantation:

i. the treatment site;

ii. the radionuclide; and

iii. the total source strength; and

b. after implantation but before the patient leaves the post-treatment recovery area:

i. the treatment site;

ii. the number of sources implanted;

iii. the total source strength implanted; and

iv. the date; or

7. for all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

a. before implantation:

i. the treatment site;

ii. the radionuclide; and

iii. the dose; and

b. after implantation but before completion of the procedure:

i. the radionuclide;

ii. the treatment site;

iii. the number of sources;

iv. the total source strength and exposure time (or the total dose); and

v. the date.

C. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of:

1. the dosage of unsealed byproduct material;

2. the brachytherapy dose;

3. the gamma stereotactic radiosurgery dose;

4. the teletherapy dose; or

5. the next fractional dose.

D. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

E. The licensee shall retain a copy of each written directive as required by this Section for three years.

F. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. the patient's or human research subject's identity is verified before each administration; and

2. each administration is in accordance with the written directive.

G. At a minimum, the procedures required by Subsection F of this Section shall address the following items that are applicable to the licensee's use of byproduct material:

1. verifying the identity of the patient or human research subject;

2. verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

3. checking both manual and computer-generated dose calculations;

4. verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by LAC 33:XV.747;

5. determining if a medical event, as described in LAC 33:XV.712, has occurred; and

6. determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

H. The licensee shall retain a copy of the procedures required under Subsection F of this Section for the duration of the license.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 21:554 (June 1995), LR 24:2110 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2591 (November 2000), LR 30:1187 (June 2004), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

**Chapter 9.** **Radiation Safety Requirements for Particle Accelerators**

**Subchapter B.** **Radiation Safety Requirements for the Use of Particle Accelerators**

**§915. Notifications, Reports, and Records of Medical Events**

A. — B. …

C. All reports, notifications, and records shall be in accordance with LAC 33:XV.712.D, E, and G.

D. …

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, LR 31:1065 (May 2005), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 47:

Chapter 15. Transportation of Radioactive Material

**§1510. General License: Use of Foreign Approved Package**

A. — D.1. …

2. complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104.B and 2113.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:1268 (June 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 34:2108 (October 2008), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 45:1183 (September 2019), LR 47:

**§1520. Quality Assurance**

A. — A.3. …

4. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices, and meeting the requirements of LAC 33:XV.547.B or equivalent NRC or other agreement state requirement, is deemed to satisfy the requirements of LAC 33:XV.1508 and LAC 33:XV.1520.A.

B. — J.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104.B and 2113.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, Legal Affairs Division, LR 34:2112 (October 2008), repromulgated LR 34:2393 (November 2008), amended by the Office of the Secretary, Legal Affairs and Criminal Investigations Division, LR 45:1184 (September 2019), LR 47:

**Family Impact Statement**

This Rule has no known impact on family formation, stability, and autonomy as described in R.S. 49:972.

**Poverty Impact Statement**

This Rule has no known impact on poverty as described in R.S. 49:973.

**Small Business Analysis**

This Rule has no known impact on small business as described in R.S. 49:978.1 - 978.8.

**Provider Impact Statement**

This Rule has no known impact on providers as described in HCR 170 of 2014.

**Public Hearing**

A public hearing will be held via Zoom on September 28, 2021, at 1:30 p.m. Interested persons are invited to attend and submit oral comments via PC, Mac, Linux, iOS or Android at https://deqlouisiana.zoom.us/j/9373792954 or by telephone by dialing 636-651-3182 using the conference code 725573. Should individuals with a disability need an accommodation in order to participate, contact Deidra Johnson at the address given below or at (225) 219-3985.

**Public Comments**

All interested persons are invited to submit written comments on the proposed regulation. Persons commenting should reference this proposed regulation by RP069ft. Such comments must be received no later than September 28, 2021, at 4:30 p.m., and should be sent to Deidra Johnson, Attorney Supervisor, Office of the Secretary, Legal Affairs and Criminal Investigations Division, P.O. Box 4302, Baton Rouge, LA 70821-4302 or to fax (225) 219-4068 or by e-mail to DEQ.Reg.Dev.Comments@la.gov. The comment period for this Rule ends on the same date as the public hearing. Copies of this proposed regulation can be purchased by contacting the DEQ Public Records Center at (225) 219-3168. Check or money order is required in advance for each copy of RP069ft. This regulation is available on the Internet at https://www.deq.louisiana.gov/page/monthly-regulation-changes-2021%20.

This proposed regulation is available for inspection at the following DEQ office locations from 8 a.m. until 4:30 p.m.: 602 N. Fifth Street, Baton Rouge, LA 70802; 1823 Highway 546, West Monroe, LA 71292; State Office Building, 1525 Fairfield Avenue, Shreveport, LA 71101; 1301 Gadwall Street, Lake Charles, LA 70615; 111 New Center Drive, Lafayette, LA 70508; 110 Barataria Street, Lockport, LA 70374; 201 Evans Road, Bldg. 4, Suite 420, New Orleans, LA 70123.

Courtney J. Burdette

General Counsel