State of Louisiana

Department of Environmental Quality

M.J. "MIKE" FOSTER, JR.
GOVERNOR

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SECRETARY

August 12, 1998

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Paul Lohaus
Deputy Director, Office of State Programs
O3H2O
US Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lohaus:

In accordance with the Guidance for Use by Agreement States for Submitting Regulations for NRC Staff Review, I have enclosed a disk containing the latest proposed regulation amendments to the Louisiana Administrative Code, Title 33, Part XV, Radiation Protection (file REGAMEND.wpd). Also on the disk is an accompanying abstract that lists and explains each amendment, including corresponding Federal Register citations (file ABSTRACT.wpd). Both items are WordPerfect 6.1 files. I have also enclosed a hard copy of our current Radiation Protection regulations for comparative purposes.

This rules package consists almost entirely of amendments that are required for purposes of compatibility (category A, B, or C). The primary exception is Chapter 17, *Licensing and Radiation Safety Requirements for Irradiators*. This Chapter conforms exactly to the Suggested State Regulations, Part Q, which the NRC has accepted as fully compatible.

All of the amendments in this package should meet NRC compatibility criteria. Wherever possible, the editor inserted the exact wording of the 10 CFR rules into the amendment, and followed Federal Register guidelines regarding Agreement State compatibility.

This package addresses all items listed in the 1995 ORNL report and NRC review of our regulations. The regulations mentioned in the report as needing to be added or amended are identified from the "NRC Chronology of Amendments" as follows:

- "Timeliness in Decommissioning of Materials Facilities," effective date August 15, 1994 (59 FR 36026)
- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," effective date January 1, 1995 (59 FR 61767, 59 FR 65243 and 60 FR 322)
- "Performance Requirements for Radiography Equipment," effective date June 30, 1995 (60 FR 28323)
- "Radiation Protection Requirements: Amended Definitions and Criteria," effective date August 14, 1995 (60 FR 36038)

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- "Clarification of Decommissioning Funding Requirements," effective date November 24, 1995 (60 FR 38235)

- "Low-Level Waste Shipment Manifest Information and Reporting," effective March 1, 1998 (60 FR 15649 and 60 FR 25983)

The following three regulation amendments are in addition to those listed in the ORNL report:

- "Medical Administration of Radiation and Radioactive Materials," effective date October 20, 1995 (60 FR 48623)

- "Criteria for the Release of Individuals Administered Radioactive Material," effective date May 29, 1997 (62 FR 4120)

- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," effective date January 2, 1998 (62 FR 63634)

Two of the regulations listed in the report were of compatibility Division 2. In these cases, Louisiana has decided to maintain our more stringent regulations:

- "Self-Guarantee as an Additional Financial Mechanism," effective date January 28, 1994 (58 FR 68726 and 59 FR 1618)

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," effective date March 13, 1995 (60 FR 7900)

This package also addresses the definition changes required or suggested in the NRC review. The wording change required for LAC 33:XV.446 was instituted in October of 1996, when Section 446 was incorporated into Section 445.

Please submit your comments on these regulations no later than October 20, 1998. If you have any questions regarding these regulation amendments, please contact me at (504) 765-0160 or Michael Defley of my staff at (504) 765-0141, or email M_DEFLEY@DEQ.STATE.LA.US.

Sincerely,

William H. Spell, Administrator
Radiation Protection Division

Enclosures:
As Stated

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 1. General Provisions

§102. Definitions and Abbreviations

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

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[See Prior Text]

Authorized Nuclear Pharmacist–a pharmacist who is:

1. board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

2. identified as an authorized nuclear pharmacist on a division, licensing state, Nuclear Regulatory Commission, or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or

3. identified as an authorized nuclear pharmacist on a permit issued by a division, licensing state, Nuclear Regulatory Commission, or agreement state specific licensee of broad scope authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

Authorized User– a physician, dentist, or podiatrist who is:

1. board certified by at least one of the boards listed in LAC 33:XV.763.C.1, D.1, E.1, F.1, H.1, or I.1;

2. identified as an authorized user on a division, licensing state, Nuclear Regulatory Commission, or agreement state license that authorizes the medical use of radioactive material; or

3. identified as an authorized user on a permit issued by a division, licensing state, Nuclear Regulatory Commission, or agreement state specific licensee of broad scope authorized to permit the medical use of radioactive material.

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[See Prior Text]

Controlled Area–an area, outside a restricted area but inside the site boundary, to which access can be limited by the licensee for any reason.

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[See Prior Text]

High-Radiation Area– an area, accessible to individuals, in which

radiation levels could result in an individual receiving a dose equivalent in excess of 100 millirems (one millisievert) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

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[See Prior Text]

Medical Use–the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user as defined in this Section.

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[See Prior Text]

Misadministration–the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

a. involving the wrong individual or wrong radiopharmaceutical; or

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[See Prior Text in 1.b]

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

a. involving the wrong individual, wrong pharmaceutical, or wrong route of administration; or

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[See Prior Text in 2.b–3]

a. involving the wrong individual or wrong treatment site; or

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[See Prior Text in 3.b–4]

a. involving the wrong individual, wrong mode of treatment, or wrong treatment site;

***

[See Prior Text in 4.b–5]

a. involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

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[See Prior Text in 5.b–6]

a. involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

b. when the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

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[See Prior Text]

Occupational Dose—the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation and/or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with LAC 33:XV.725, from voluntary participation in medical research programs, or as a member of the public.

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[See Prior Text]

Pharmacist—any individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

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[See Prior Text]

Principal Activities—activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

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[See Prior Text]

Public Dose—the dose received by a member of the public from exposure to sources of radiation and/or radioactive material released from licensed or registered operations. Public dose does not include occupational dose, dose received from background radiation, dose received from any medical administration the individual has received, dose received from exposure to individuals administered radioactive material and released in accordance with LAC 33:XV.725, or dose received from voluntary participation in medical research programs.

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[See Prior Text]

Radiation Area—an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of five millirems (0.05 millisievert) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates, or in any five consecutive days, a dose in excess of 100 millirems (one millisievert).

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[See Prior Text]

Radiological Physicist–an individual who:

1. is certified in Therapeutic Radiological Physics or Radiological Physics by the American Board of Radiology, or in radiation oncology physics by the American Board of Medical Physics; or

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[See Prior Text in 2–3]

Recordable Event–in medical procedures, the administration of:

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[See Prior Text in 1–4]

5. a teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more; or

6. a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

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[See Prior Text]

Restricted Area–an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

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[See Prior Text]

Survey–an evaluation of the production, use, release, disposal, transfer, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to, tests, physical examination, and measurements of levels of radiation or concentrations of radioactive materials present.

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[See Prior Text]

Unrestricted Area (an Uncontrolled Area)–an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

Waste–those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act,

P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste:

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

2. classified as low-level radioactive waste consistent with existing law and in accordance with Paragraph 1 above by the U.S. Nuclear Regulatory Commission.

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[See Prior Text]

Working Level (WL)—any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3×10^5 MeV of alpha particle energy.

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[See Prior Text]

Written Directive—an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in Paragraph 6 of this definition, containing the following information:

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[See Prior Text in *Written Directive*.1-*Year*]

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

HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 19:1421 (November 1993), LR 20:650 (June 1994), LR 22:967 (October 1996), amended LR 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 3. Licensing of Radioactive Material

§304. Radioactive Material Other Than Source Material

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[See Prior Text in A–C.4]

5. Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans

a. Except as provided in Subsection C.5.b and c of this Section, any person is exempt from the requirements for a license set forth in these regulations provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1µCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process), for "in vivo" diagnostic use for humans.

b. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license in accordance with LAC 33:XV.Chapters 3 and 7.

c. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license in accordance with LAC 33:XV.328.K.

d. Nothing in this Section relieves persons from complying with applicable FDA, other federal, and state requirements governing receipt, administration, and use of drugs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§325. General Requirements for the Issuance of Specific Licenses

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[See Prior Text in A–D.2.a]

b. submit a certification that financial assurance arrangement for decommissioning has been provided in the amount prescribed by Subsection D.4 of this Section using one of the methods described in Subsection D.6 of this Section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued, but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection D.6 of this Section shall be submitted to the division before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the division, as part of the certification, a copy of the financial instrument obtained to satisfy the requirements of Subsection D.6 of this Section .

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[See Prior Text in D.3–3.a]

b. Each holder of a specific license issued before the effective date of these regulations and of a type described in Subsection D.1 of this Section shall submit, on or before July 20, 1992, a decommissioning funding plan, as described in Subsection D.6 of this Section, or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this Section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

c. Each holder of a specific license issued before the effective date of these regulations and of a type described in Subsection D.2 of this Section shall submit, on or before July 20, 1992, a certification of financial assurance for decommissioning, or a decommissioning funding plan, as described in Subsection D.6 of this Section, in accordance with the criteria set forth in this Section.

d. Any licensee who has submitted an application before July 20, 1992, for renewal of license in accordance with LAC 33:XV.333 shall provide financial assurance for decommissioning in accordance with Subsection D.1 and 2 of this Section. This assurance shall be submitted when this rule becomes effective.

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[See Prior Text in D.4–4.c]

5. Each decommissioning funding plan shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection D.6 of this Section, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility. The decommissioning funding plan shall also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of Subsection D.6 of this Section.

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[See Prior Text in D.6–7.d.iv]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 23:1140 (September 1997), amended LR 24:**.

§326. Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

A. Specific Licenses for Irradiators. The division shall approve an application for a specific license for the use of licensed material in an irradiator in accordance with LAC 33:XV.Chapter 17, if the applicant meets the following requirements:

1. the applicant shall satisfy the general requirements specified in LAC 33:XV.Chapter 3;

2. the application shall describe the training provided to irradiator operators including:

a. classroom training;
b. on-the-job or simulator training;
c. safety reviews;
d. means employed by the applicant to test each operator's understanding of the division's regulations and licensing requirements and the irradiator operating, safety, and emergency procedures; and
e. minimum training and experience of personnel who may provide training;

3. the application shall include an outline of the written operating and emergency procedures listed in LAC 33:XV.1735 that describes the radiation safety aspects of the procedures;

4. the application shall describe the organizational structure for managing the irradiator, specifically, the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have radiation safety responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of radiation safety officer;

5. the application shall include a description of the access control systems required by LAC 33:XV.1713, the radiation monitors required by LAC 33:XV.1719, the method of detecting leaking sources required by LAC 33:XV.1741, including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors;

6. if the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry-source-storage sealed sources and submit a description of these procedures to the division. The description shall include:

a. methods of collecting the leak test samples;
b. qualifications of the individual who collects the samples;

c. instruments to be used; and
d. methods of analyzing the samples;

7. if licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by a person specifically authorized by the division, the Nuclear Regulatory Commission, an agreement state, or a licensing state to load or unload irradiator sources; and

8. the applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by LAC 33:XV.1743.

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[See Prior Text in B–E.1.f]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

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

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[See Prior Text in A–I.1.b]

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

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

a. the applicant satisfies the general requirements for the issuance of specific licenses specified in LAC 33:XV.325;

b. the applicant submits evidence that the applicant is at least one of the following:

i. registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

ii. registered or licensed with a state agency as a drug manufacturer;

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

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

c. the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the radioactive material that is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

d. the labeling meets the following criteria:

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;

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; and

iii. the labels, leaflets, or brochures required by this Section are in addition to the labeling required by the U.S. Food and Drug Administration (FDA), and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

2. A licensee described by Subsection J.1.b.iii or iv of this Section:

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

b. may allow a pharmacist to work as an authorized nuclear pharmacist if:

i. this individual qualifies as an authorized nuclear pharmacist as defined in LAC 33:XV.102;

ii. this individual meets the requirements specified in LAC 33:XV.763.J and K.2 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

c. may conduct the actions authorized in Subsection J.2.a and b of this Section in spite of more restrictive language in license conditions;

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

e. shall provide to the division a copy of each individual's certification by the Board of Pharmaceutical Specialties and the division, licensing state, Nuclear Regulatory Commission, or agreement state license or the permit issued by a licensee of broad scope and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist, in accordance with Subsection J.2.b.i and iii of this Section.

3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-emitting, beta-emitting, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

a. perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

b. check each instrument for constancy and proper operation at the beginning of each day of use.

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

K. License Requirements for the Manufacture, Preparation, or Transfer for Commercial Distribution of Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans

1. An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1μCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing process) for "in vivo" diagnostic use, to persons exempt from licensing under LAC 33:XV.304.C.5 will

be approved if:

a. the applicant satisfies the general requirements specified in LAC 33:XV.325;

b. the applicant meets the requirements under Subsection J.1.b of this Section;

c. the applicant provides evidence that each capsule contains 37 kBq (1µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

d. the carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this Section), or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

e. the carbon-14 urea is in the form of a capsule, is identified as radioactive, and is to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. The capsule shall meet the following conditions:

i. the immediate container of the capsule(s) bears a durable, legible label that:

(a). identifies the radioisotope, the physical and chemical form, and the quantity of radioactivity of each capsule at a specific date; and

(b) bears the words "Radioactive Material";

ii. in addition to the labeling information required by Subsection K.1.e.i of this Section, an accompanying brochure or the label affixed to the immediate container also:

(a). states that the contents are exempt from division licensing requirements; and

(b). bears the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Shall Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash"; and

f. the applicant submits copies of prototype labels and brochures and the division approves these labels and brochures.

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

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[See Prior Text in L–M.4.g]

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

HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§332. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

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[See Prior Text in A–D.1.e.ii]

2. Plan for Completion of Decommissioning

a. In addition to the information required under Subsection D.1.d

and e of this Section, the licensee shall submit a plan for completion of decommissioning, if required by the license condition or if the procedures necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the division and could increase potential health and safety impacts to workers or to the public such as in any of the following cases:

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[See Prior Text in D.2.a.i–c.ii]

iii. a description of the planned final radiation survey;

iv. an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning;

v. a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan; and

vi. for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, a justification for the delay based on the criteria in Subsection D.2.c.v of this Section.

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[See Prior Text in D.2.d–5.b]

c. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the division determines that:

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[See Prior Text in D.5.c.i–c.ii.(b)]

6. Timeliness of Decommissioning

a. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the division in writing of such occurrence and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release for unrestricted use, or submit within 12 months of notification a decommissioning plan, if required by Subsection D.2 of this Section, and begin decommissioning upon approval of that plan if:

i. the license has expired in accordance with Subsection A of this Section;

ii. the licensee has decided to permanently cease principal activities, as defined in LAC 33:XV.102, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use;

iii. no principal activities under the license have been conducted for a period of 24 months; or

iv. no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use.

b. Coincident with the notification required by Subsection D.6.a of this Section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee in accordance with LAC

33:XV.351 in conjunction with a license issuance or renewal or as required by this Section. The amount of the financial assurance shall be increased or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established in accordance with Subsection D.2.c.iv of this Section.

i. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective.

ii. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the division.

c. The division may grant a request to extend the time periods established in Subsection D.6.a of this Section if the division determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request shall be submitted no later than 30 days before notification in accordance with Subsection D.6.a of this Section. The schedule for decommissioning set forth in Subsection D.6.a of this Section may not commence until the division has made a determination on the request.

d. The division may approve an alternative schedule for submittal of a decommissioning plan required in accordance with Subsection D.6.a of this Section if the division determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

e. Decommissioning Time Limit

i. Except as provided in Subsection D.6.e.iii of this Section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable, but no later than 24 months following the initiation of decommissioning.

ii. Except as provided in Subsection D.6.e.iii of this Section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable, but no later than 24 months following the initiation of decommissioning.

iii. The division may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area and license termination, if appropriate, if the division determines that the alternative is warranted by consideration of the following:

(a). whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(b). whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(c). whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d). whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e). other site-specific factors that the division may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than deferred cleanup, and other factors

beyond the control of the licensee.

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[See Prior Text in E–E.2]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

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Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 4. Standards for Protection Against Radiation

Subchapter A. General Provisions

§402. Scope

Except as specifically provided in other chapters of these regulations, this Chapter applies to persons licensed or registered by the division to receive, possess, use, transfer, or dispose of sources of radiation or to operate a production or utilization facility under these regulations. The limits in this Chapter do not apply to doses due to background radiation, to exposure from any medical administration the individual has received, to exposure from individuals administered radioactive material and released in accordance with LAC 33:XV.725, or to exposure from voluntary participation in medical research programs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended LR 24:**.

Subchapter B. Radiation Protection Programs

§414. Determination of Prior Occupational Dose

A. For each individual who is likely to receive, in a year, an occupational dose requiring monitoring in accordance with LAC 33:XV.431, the licensee or registrant shall:

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[See Prior Text in A.1-G]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:970 (October 1996), amended LR 24:**.

§421. Radiation Dose Limits for Individual Members of the Public

A. Each licensee or registrant shall conduct operations so that:

1. except as provided in Subsection A.3 of this Section, the total effective dose equivalent (TEDE) to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, any medical administration the individual has received, voluntary participation in medical research programs, exposure to individuals administered radioactive material and released in accordance with LAC 33:XV.725, and the licensee's or registrant's disposal of radioactive material into sanitary sewerage in

accordance with LAC 33:XV.462[3];

2. the dose in any unrestricted area from external sources, exclusive of the dose contributions from individuals administered radioactive material and released in accordance with LAC 33:XV.725, does not exceed 0.02 mSv (0.002 rem) in any one hour; and

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[See Prior Text in A.3-E]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:970 (October 1996), amended LR 24:**.

Subchapter F. Storage and Control of Licensed or Registered Sources of Radiation

§445. Security of Stored Sources of Radiation

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[See Prior Text in A]

B. The licensee or registrant shall maintain constant surveillance or use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in a controlled or unrestricted area and that is not in storage.

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[See Prior Text in C-D]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:972 (October 1996), amended LR 24:**.

Subchapter G. Precautionary Procedures

§452. Exceptions to Posting Requirements

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[See Prior Text in A-A.2]

B. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs in accordance with LAC 33:XV.451, provided that the patient cannot be released from licensee control in accordance with LAC 33:XV.725 and 745.

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[3]Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of 5 mSv (0.5 rem) in a year.

[See Prior Text in C-E]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:972 (October 1996), LR 24:**.

Subchapter H. Waste Disposal

§465. Transfer for Disposal and Manifests

A. The requirements of this Section and Appendices D and E of this Chapter are designed to: control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix D of this Chapter, who ships low-level waste either directly or indirectly through a waste collector or waste processor to a licensed low-level radioactive waste disposal facility; establish a manifest tracking system; and supplement existing requirements concerning transfers and recordkeeping for those wastes.

B. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest in accordance with Appendix D of this Chapter.

C. Each shipment manifest shall include a certification by the waste generator in accordance with Appendix D of this Chapter.

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Appendix D of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended LR 24:**.

Subchapter I. Records

§470. General Provisions

A. Each licensee or registrant shall use the International System of Units (SI) units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Chapter. Notwithstanding these allowances, when recording information on shipment manifests, as required in LAC 33:XV.465, information shall be recorded in SI or in both SI and special units.

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[See Prior Text in B]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,

Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), amended LR 24:**.

APPENDIX D
REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

A. Manifest. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility shall prepare a manifest (OMB Control Numbers 3150 - 0164, - 0165, and - 0166) reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A shall be completed and shall physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541, 541A, 542, and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms.

1. Licensees are not required by the division to comply with the manifesting requirements of this Appendix when they ship:

a. LLW (Low-Level Waste) for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

b. LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

c. radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

B. For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this Appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

C. NRC Forms 540, 540A, 541, 541A, 542, and 542A, and the accompanying instructions in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415 - 7232.

D. This Appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261, or elsewhere, is not addressed in this Appendix, and shall be provided on the required EPA forms. However, the required EPA forms shall accompany the Uniform Low-Level Radioactive Waste Manifest required by this Appendix and LAC 33:XV.Chapter 4.

E. As used in this Appendix, the following definitions apply:

Chelating Agent—see definition in LAC 33:XV.102.

Chemical Description—a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-Readable Medium—a medium from which the division's computer can

transfer the information from the medium to its memory. This medium shall be in an ASCII compatible format.

Consignee—the designated receiver of the shipment of low-level radioactive waste.

Decontamination Facility—a facility operating under a division, Nuclear Regulatory Commission, or agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives and, for purposes of this Appendix, is not considered to be a consignee for LLW shipments.

Disposal Container—a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

Electronic Media—media from which the division's computer can transfer the information from the media into its memory. This media shall be in an ASCII compatible format.

EPA Identification Number—the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator—a licensee operating under a division, Nuclear Regulatory Commission, or agreement state license who is a waste generator as defined in this Appendix, or is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High Integrity Container (HIC)—a container commonly designed to meet the structural stability requirements of Appendix E of this Chapter and to meet Department of Transportation requirements for a Type A package.

Land Disposal Facility—see definition in LAC 33:XV.1302.

Low-Level Waste (LLW)—see definition of *waste* in LAC 33:XV.102.

NRC Forms 540, 540A, 541, 541A, 542, and 542A—official NRC forms referenced in this Appendix. Licensees need not use originals of these NRC forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media shall have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package—the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical Description—the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual Waste–low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper–the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping Paper–NRC Form 540 and, if required, NRC form 540A, which includes the information required by DOT in 49 CFR part 172.

Source Material–see definition in LAC 33:XV.102.

Special Nuclear Material–see definition in LAC 33:XV.102.

Uniform Low-level Radioactive Waste Manifest or Uniform Manifest–the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste–see definition in LAC 33.XV.102

Waste Collector–an entity, operating under a division, Nuclear Regulatory Commission, or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste Description–the physical, chemical, and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste Generator–an entity, operating under a division, Nuclear Regulatory Commission, or agreement state license, who possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use and transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste Processor–an entity, operating under a division, Nuclear Regulatory Commission, or agreement state license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste Type–a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description or a waste sorbed on or solidified in a specifically defined media).

F. Information Requirements

1. General Information. The shipper of the radioactive waste shall

provide the following information on the uniform manifest:

a. the name, facility address, and telephone number of the licensee shipping the waste;

b. an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

c. the name, address, and telephone number or the name and EPA identification number for the carrier transporting the waste.

2. Shipment Information. The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

a. the date of the waste shipment;

b. the total number of packages/disposal containers;

c. the total disposal volume and disposal weight in the shipment;

d. the total radionuclide activity in the shipment;

e. the activity of each of the radionuclides, H - 3, C - 14, Tc-99, and I - 129, contained in the shipment; and

f. the total masses of U - 233, U - 235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

3. Disposal Container and Waste Information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

a. an alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

b. a physical description of the disposal container, including the manufacturer and model of any high integrity container;

c. the volume displaced by the disposal container;

d. the gross weight of the disposal container, including the waste;

e. for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

f. a physical and chemical description of the waste;

g. the total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

h. the approximate volume of waste within a container;

i. the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

j. the identities and activities of individual radionuclides contained in each container, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

k. the total radioactivity within each container; and

l. for wastes consigned to a disposal facility, the classification of the waste in accordance with Appendix E of this Chapter. Waste not meeting the structural stability requirements of Appendix E of this Chapter shall be identified.

4. Uncontainerized Waste Information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

a. the approximate volume and weight of the waste;
b. a physical and chemical description of the waste;
c. the total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;
d. for waste consigned to a disposal facility, the classification of the waste in accordance with Appendix E of this Chapter. Waste not meeting the structural stability requirements of Appendix E of this Chapter shall be identified;
e. the identities and activities of individual radionuclides contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and
f. for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

5. Multi-Generator Disposal Container Information. This Paragraph applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators," including "waste generators," as defined in this Appendix.) It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators. The shipper of radioactive waste shall provide the following information on the manifest regarding waste shipments containing mixtures of waste originating from multiple generators:

a. for homogeneous mixtures of waste, such as incinerator ash, the waste description applicable to the mixture and the volume of the waste attributed to each generator;
b. for heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container and, for discrete waste types (e.g., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:
i. the volume of waste within the disposal container;
ii. a physical and chemical description of the waste, including the solidification agent, if any;
iii. the total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;
iv. the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix E of this Chapter; and
v. radionuclide identities and activities contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

G. Certification. An authorized representative of the waste generator,

processor, or collector shall certify, by signing and dating the shipment manifest, that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the division. A collector, in signing the certification, is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

H. Control and Tracking

1. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector or any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the following requirements:

a. prepare all wastes so that the waste is classified and meets the waste characteristics requirements according to Appendix E of this Chapter;

b. label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with Appendix E of this Chapter;

c. conduct a quality assurance program to assure compliance with Appendix E of this Chapter (the program shall include management evaluation of audits);

d. prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this Appendix;

e. forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: receipt of the manifest precedes the LLW shipment; or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both options is also acceptable;

f. include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in Subsection H.1.e of this Appendix;

g. receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

h. retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by LAC 33:XV.Chapter 3; and

i. for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Subsection H.5 of this Appendix.

2. Any waste collector licensee who handles only prepackaged waste shall:

a. acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

b. prepare a new manifest to reflect consolidated shipments that meet the requirements of this Appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

c. forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: receipt of the manifest precedes the LLW shipment; or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the

consignee. Using both options is also acceptable;

d. include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in Subsection H.2.c of this Appendix;

e. receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

f. retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material, as required by LAC 33:XV.Chapter 3;

g. for any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Subsection H.5 of this Appendix; and

h. notify the shipper and the division when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

3. Any licensed waste processor who treats or repackages waste shall:

a. acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

b. prepare a new manifest that meets the requirements of this Appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in Subsection F.5 of this Appendix;

c. prepare all wastes so that the waste is classified and meets the waste characteristics requirements according to Appendix E of this Chapter;

d. label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix E of this Chapter;

e. conduct a quality assurance program to assure compliance with Appendix E of this Chapter (the program shall include management evaluation of audits);

f. forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: receipt of the manifest precedes the LLW shipment; or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both options is also acceptable;

g. include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in Subsection H.3.f of this Appendix;

h. receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

i. retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material, as required by LAC 33:XV.Chapter 3;

j. for any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Subsection H.5 of this Appendix; and

k. notify the shipper and the division when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

4. The land disposal facility operator shall:

a. acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms shall be returned indicating the discrepancy;

b. maintain copies of all completed manifests and electronically store the information required by LAC 33:XV.1333.G until the division terminates the license; and

c. notify the shipper and the division when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

5. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this Appendix shall:

a. be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

b. be traced and reported. The investigation shall include tracing the shipment and filing a report with the division. Each licensee who conducts a trace investigation shall file a written report with the division within two weeks of completion of the investigation.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 5. Radiation Safety Requirements For Industrial Radiographic Operations

§550. Performance Requirements for Radiography Equipment

Equipment serviced, maintained, or repaired by a licensee or registrant or used in industrial operations must meet the following minimum criteria:

1. each radiographic exposure device and all associated equipment shall meet the requirements specified in American National Standard (ANSI) N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). Engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the division may find this an acceptable alternative to actual testing of the component in accordance with the referenced standard;

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[See Prior Text in 2-3.h]

i. source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly;

j. malfunction of any exposure device or associated equipment shall be reported to the division in accordance with the requirements of LAC 33:XV.341; and

k. notwithstanding Subsection A.1, 4, and 5 of this Section, equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in American National Standards Institute N432 - 1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

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[See Prior Text in 4-5]

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 20:653 (June 1994), amended LR 21:554 (June 1995), LR 23:1138 (September 1997), amended LR 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 7. Use of Radionuclides in the Healing Arts

Note: LAC 33:XV.763–775 have been moved and renumbered as subsections of revised LAC 33:XV.763. This was necessary to accommodate NRC-mandated insertions. The changes involved are as follows: LAC 33:XV.763 to 763.A; 764 to 763.B; 765 to 763.C; 766 to 763.D; 767 to 763.E; 768 to 763.F; 769 to 763.G; 770 to 763.H; 771 to 763.I; 772 to 763.J; 773 to 763.M; 774 to 763.N; and 775 to 763.O.

§701. Purpose and Scope

This Chapter establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this Chapter are in addition to, and not in substitution for, other applicable provisions of LAC 33:XV.Chapters 1, 3, 4, and 10. The requirements and provisions of these regulations apply to applicants and licensees subject to this Chapter unless specifically exempted. The definitions of some terms used in this Chapter may be found in LAC 33:XV.Chapters 1 and 6. Nothing in this Chapter relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs or devices.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§702. License Required and Exemptions

A. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the division, the Nuclear Regulatory Commission, or an agreement state or as allowed in Subsections B and C of this Section.

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[See Prior Text in B]

C. An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this Chapter under the supervision of an authorized nuclear pharmacist or authorized user, as provided in LAC 33:XV.709, unless prohibited by license condition.

D. Exemptions Regarding Specific Licenses of Broad Scope. A licensee possessing a specific license of broad scope for medical use is exempt from the following:

1. the provisions of LAC 33:XV.703.A.2;

2. the provisions of LAC 33:XV.703.A.5 regarding additions to or changes in the areas of use only at the addresses specified in the license;

3. the provisions of LAC 33:XV.704.A; and

4. the provisions of LAC 33:XV.704.B.1 for an authorized user or an authorized nuclear pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§703. License Amendments and Provisions for Research Involving Human Subjects

A. A licensee shall apply for and receive a license amendment:

1. before using radioactive material for a method or type of medical use not permitted by the license issued under this Chapter;

2. before permitting anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

a. an authorized user certified by the organizations specified in LAC 33:XV.763.C.1, D.1, E.1, F.1, H.1, or I.1;

b. an authorized nuclear pharmacist certified by the organization specified in LAC 33:XV.763.K.1;

c. identified as an authorized user or an authorized nuclear pharmacist on a division, Nuclear Regulatory Commission, licensing state, or agreement state license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

d. identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a division, Nuclear Regulatory Commission, licensing state, or agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

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[See Prior Text in A.3–6]

B. Provisions for Research Involving Human Subjects. A licensee may conduct research involving human subjects using radioactive material, provided that the research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its division license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§704. Notifications

A. A licensee shall provide to the division a copy of the board

certification, the Nuclear Regulatory Commission, or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist in accordance with LAC 33:XV.703.A.2.

B. A licensee shall notify the division by letter no later than 30 days after:

1. an authorized user, an authorized nuclear pharmacist, a radiation safety officer, or a teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

2. the licensee's mailing address changes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§707. Radiation Safety Committee

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[See Prior Text in A–A.2.a]

b. i. review, on the basis of safety and with regard to the training and experience standards of this Chapter, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; and

ii. review, in accordance with LAC 33:XV.703.A.2, on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

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[See Prior Text in A.2.c–h]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§709. Supervision

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[See Prior Text in A–B.3]

C. A licensee that permits the preparation of by-product material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by LAC 33:XV.702, shall:

1. instruct the supervised individual in the preparation of by-product material for medical use and the principles of and procedures for

radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of by-product material;

2. require the supervised individual to follow the instructions given in accordance with Subsection C.1 of this Section and to comply with the regulations of this Chapter and license conditions; and

3. require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing by-product material for medical use and the records kept to reflect that work.

D. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§710. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), repealed LR 24:**

§712. Notifications, Reports, and Records of Misadministrations

A. For a misadministration:

1. the licensee shall notify by telephone the division no later than the next calendar day after discovery of the misadministration;

2. the licensee shall submit a written report to the division within 15 days after discovery of the misadministration. The written report shall include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the administration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, or the individual's responsible relative or guardian (this person will be subsequently referred to as "the individual" in this Section), and if not, why not, and if the individual was notified, what information was provided to the individual. The report shall not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this Section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate;

3. the licensee shall notify the referring physician and also notify the individual receiving the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he 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 individual receiving the misadministration 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 misadministration, because of any delay in notification;

4. if the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

a. a copy of the report that was submitted to the division; or

b. a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the division can be obtained from the licensee.

B. Each licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician), the individual's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

C. 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§713. Suppliers

A licensee shall use for medical use only:

1. radioactive material, including sealed sources or devices, manufactured, labeled, packaged, and distributed in accordance with a license issued in accordance with these regulations or the equivalent regulations of another agreement state, a licensing state, or the Nuclear Regulatory Commission;

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[See Prior Text in 2-3]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§715. Possession, Use, Calibration, and Check of Dose Calibrators and of Instruments to Measure Dosages of Alpha-Emitting or Beta-Emitting Radionuclides

A. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or

human research subject.

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[See Prior Text in B-E.4]

F. Possession, Use, Calibration, and Check of Instruments to Measure Dosages of Alpha-Emitting or Beta-Emitting Radionuclides

1. This Subsection does not apply to unit dosages of alpha-emitting or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed in accordance with LAC 33:XV.Chapter 3, equivalent agreement state, or Nuclear Regulatory Commission requirements.

2. For other than unit dosages obtained in accordance with Subsection F.1 of this Section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha-emitting or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-emitting or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

a. perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument and make adjustments when necessary; and

b. check each instrument for constancy and proper operation at the beginning of each day of use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§717. Assay of Radiopharmaceutical Dosages

A licensee shall do the following:

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[See Prior Text in A-B]

C. Assay before medical use, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha-emitting or a beta-emitting radionuclide, except for unit dosages obtained from a manufacturer or preparer licensed in accordance with LAC 33:XV.Chapter 3, equivalent agreement state, or Nuclear Regulatory Commission requirements.

D. Retain a record of the assays required by Subsections A, B, and C of this Section for two years. To satisfy this requirement, the record shall contain the following:

1. generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; and expiration dates and the radionuclide;

2. patient's or human research subject's name and identification number if one has been assigned;

3. prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 microcuries (370 Kbq);

4. date and time of the assay and administration; and

5. initials of the individual who performed the assay.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§720. Syringe Shields

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[See Prior Text in A]

B. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), repealed and repromulgated by the Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§721. Syringe Labels

Unless it is utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§725. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants

A. A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

B. A licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective

dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. guidance on the interruption or discontinuation of breast-feeding; and

2. information on the consequences of failure to follow the guidance.

C. The licensee shall maintain a record of the basis for authorizing the release of an individual for three years after the date of release, if the total effective dose equivalent is calculated by:

1. using the retained activity rather than the activity administered;

2. using an occupancy factor less than 0.25 at one meter;

3. using the biological or effective half-life; or

4. considering the shielding by tissue.

D. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

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

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[See Prior Text in A-B]

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

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

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.C, or an individual under the supervision of either as specified in LAC 33:XV.709.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

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

and Localization Studies

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[See Prior Text in A–E]

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

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

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.C, or an individual under the supervision of either as specified in LAC 33:XV.709.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§735. Use of Radiopharmaceuticals for Therapy

A. A licensee may use the following prepared radiopharmaceuticals:

1. iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;

2. phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;

3. phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

4. any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

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

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

2. prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in LAC 33:XV.763.C, or an individual under the supervision of either as specified in LAC 33:XV.709.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of

Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§736. Safety Instruction

A. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

B. To satisfy Subsection A of this Section, the instruction shall describe the licensee's procedures for:

1. patient or human research subject control;

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[See Prior Text in B.2–4]

5. notification of the radiation safety officer or authorized user in the case of the patient's or human research subject's death or medical emergency; and

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[See Prior Text in B.6–C]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§737. Safety Precautions

A. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with LAC 33:XV.725, a licensee shall do the following:

1. provide a private room with a private sanitary facility;

2. post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

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[See Prior Text in A.3–4]

5. either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

6. survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection

survey instrument before assigning another patient or human research subject to the room. The room shall not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

7. submit to the division an acceptable procedure to measure the thyroid burden of each individual who helps prepare or administer a dosage of iodine-131. Measurements shall be performed within three days after administering the dosage, and records shall include each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. The records shall be retained for the period required by LAC 33:XV.472.B.

B. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§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 implant therapy. Refresher training shall be provided at intervals not to exceed one year.

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[See Prior Text in B-B.2]

3. procedures for patient or human research subject control;

4. procedures for visitor control;

5. procedures for notification of the radiation safety officer or authorized user if the patient or human research subject dies or has a medical emergency; and

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[See Prior Text in B.6-C]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§743. Safety Precautions

A. For each patient or human research subject receiving implant therapy and not released from licensee control in accordance with LAC 33:XV.725, a licensee shall:

1. not quarter the patient or human research subject in the same room as an individual who is not receiving radiation therapy;

2. post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

3. authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer; and

4. promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with LAC 33:XV.415.A and retain for two years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in milliroentgens per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

B. A licensee shall notify the radiation safety officer or authorized user immediately if the patient or human research subject dies or has a medical emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§744. Brachytherapy Sources Inventory

A. Promptly after removing them 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.

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[See Prior Text in B–B.1]

2. the number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

3. the number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

C. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or

human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

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[See Prior Text in D]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§745. Release of Patients or Human Research Subjects Treated with Temporary Implants

A. 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. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

B. A licensee shall maintain a record of patient or human research subject surveys that demonstrates compliance with Subsection A of this Section for two years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as milliroentgens per hour and measured within one meter from the patient or human research subject, and the initials of the individual who made the survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§750. Safety Instruction

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[See Prior Text in A]

1. the procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

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[See Prior Text in A.2–C]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§753. Radiation Monitoring Device

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[See Prior Text in A–C]

D. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

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[See Prior Text in E–G]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§754. Viewing System

A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§763. Training

A. Radiation Safety Officer. Except as provided in Subsection B of this Section, an individual fulfilling the responsibilities of the radiation safety officer as provided in LAC 33:XV.706 shall:

1. be certified by the:
   a. American Board of Health Physics in Comprehensive Health Physics;
   b. American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;
   c. American Board of Nuclear Medicine;
   d. American Board of Science in Nuclear Medicine;
   e. Board of Pharmaceutical Specialties in Nuclear Pharmacy;
   f. American Board of Medical Physics in Radiation Oncology Physics;
   g. Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;
   h. American Osteopathic Board of Radiology; or
   i. American Osteopathic Board of Nuclear Medicine; or

2. have had 200 hours of classroom and laboratory training as follows:
   a. radiation physics and instrumentation;
   b. radiation protection;
   c. mathematics pertaining to the use and measurement of radioactivity;
   d. radiation biology;
   e. radiopharmaceutical chemistry; and
   f. one year of full-time experience in radiation safety at a

medical institution under the supervision of the individual identified as the radiation safety officer on a division, agreement state, licensing state, or Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

3. be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

B. Experienced Radiation Safety Officer. An individual identified as a radiation safety officer on a division, agreement state, licensing state, or Nuclear Regulatory Commission license on February 20, 1991, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of Subsection A of this Section.

C. Uptake, Dilution, or Excretion Studies. Except as provided in Subsections M and N of this Section, the licensee shall require the authorized user of a radiopharmaceutical listed in LAC 33:XV.729 to be a physician who:

1. is certified in:
   a. nuclear medicine by the American Board of Nuclear Medicine;
   b. diagnostic radiology by the American Board of Radiology;
   c. diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology;
   d. nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
   e. nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.
   a. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:
      i. radiation physics and instrumentation;
      ii. radiation protection;
      iii. mathematics pertaining to the use and measurement of radioactivity;
      iv. radiation biology; and
      v. radiopharmaceutical chemistry.
   b. To satisfy the requirement for 20 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
      i. examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
      ii. selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
      iii. administering dosages to patients or human research subjects and using syringe radiation shields;
      iv. collaborating with the authorized user in the interpretation of radionuclide test results; and
      v. patient or human research subject follow-up; or

3. has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accredi-

tation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in Subsection C.2.b. of this Section.

D. Imaging and Localization Studies. Except as provided in Subsections M and N of this Section, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in LAC 33:XV.731 to be a physician who:

1. is certified in:
   a. nuclear medicine by the American Board of Nuclear Medicine;
   b. diagnostic radiology by the American Board of Radiology;
   c. diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology;
   d. nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
   e. nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits; 500 hours of supervised work experience; and 500 hours of supervised clinical experience.
   a. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:
      i. radiation physics and instrumentation;
      ii. radiation protection;
      iii. mathematics pertaining to the use and measurement of radioactivity;
      iv. radiopharmaceutical chemistry;
      v. radiation biology; and
      vi. certification by the physician that he or she participated in the required number of hours and has successfully passed an appropriate written examination given by the certifying institution.
   b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
      i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
      ii. calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
      iii. calculating and safely preparing patient or human research subject dosages;
      iv. using administrative controls to prevent the misadministration of radioactive material;
      v. using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
      vi. eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radio-pharmaceuticals.
   c. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
      i. examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide

diagnosis, limitations, or contraindications;

ii. selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

iii. administering dosages to patients or human research subjects and using syringe radiation shields;

iv. collaborating with the authorized user in the interpretation of radionuclide test results; and

v. patient or human research subject follow-up; or

3. has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in Subsection D.2 of this Section.

E. Therapeutic Use of Radiopharmaceuticals. Except as provided in Subsection M of this Section, the licensee shall require the authorized user of a radiopharmaceutical listed in LAC 33:XV.735 for therapy to be a physician who:

1. is certified by:

a. the American Board of Nuclear Medicine;

b. the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

c. the Royal College of Physicians and Surgeons of Canada in nuclear medicine; or

d. the American Osteopathic Board of Radiology after 1984; or

2. has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals and has had supervised clinical experience.

a. To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology.

b. To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

i. use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

ii. use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

iii. use of iodine-131 for treatment of thyroid carcinoma in three individuals; and

iv. use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.

F. Therapeutic Use of Brachytherapy Sources. Except as provided in Subsection M of this Section, the licensee shall require the authorized user using a brachytherapy source specified in LAC 33:XV.741 for therapy to be a physician who:

1. is certified in:

a. radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

b. radiation oncology by the American Osteopathic Board of Radiology;

c. radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

2. is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

a. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology.

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

i. ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. checking survey meters for proper operation;

iii. preparing, implanting, and removing sealed sources;

iv. using administrative controls to prevent the misadministration of radioactive material; and

v. using emergency procedures to control radioactive material.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

i. examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

ii. selecting the proper brachytherapy sources, dose, and method of administration;

iii. calculating the dose; and

iv. post-administration follow-up and review of case histories in collaboration with the authorized user.

G. Ophthalmic Use of Strontium-90. Except as provided in Subsection M of this Section, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

1. is certified in radiology, therapeutic radiology, or radiation

oncology by the American Board of Radiology; or

2. is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology.

b. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

i. examination of each individual to be treated;

ii. calculation of the dose to be administered;

iii. administration of the dose; and

iv. follow-up and review of each individual's case history.

H. Use of Sealed Sources for Diagnosis. Except as provided in Subsection M of this Section, the licensee shall require the authorized user using a sealed source in a device specified in LAC 33:XV.739 to be a physician, dentist, or podiatrist who:

1. is certified in:

a. radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

b. nuclear medicine by the American Board of Nuclear Medicine;

c. diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

d. nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

2. has completed 80 hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

a. To satisfy the requirement for instruction, the training shall include:

i. radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

ii. radiation biology; and

iii. radiation protection and training in the use of the device for the purposes authorized by the license.

I. Teletherapy Except as provided in Subsection M of this Section, the licensee shall require the authorized user of a sealed source specified in LAC 33:XV.747 in a teletherapy unit to be a physician who:

1. is certified in:

a. radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

b. radiation oncology by the American Osteopathic Board of Radiology;

c. radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

d. therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

2. is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. radiation biology.

b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

i. review of the full calibration measurements and periodic spot-checks;

ii. preparing treatment plans and calculating treatment times;

iii. using administrative controls to prevent misadministrations;

iv. implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

v. checking and using survey meters.

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

i. examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

ii. selecting the proper dose and how it is to be administered;

iii. calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reactions to radiation; and

iv. post-administration follow-up and review of case histories.

J. Teletherapy Physicist. A teletherapy physicist shall meet the criteria in the definition of *Radiological Physicist* in LAC 33:XV.Chapter 1.

K. Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who either:

1. has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

2. has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy and that the individual has completed 700 hours in a structured educational program consisting of both:

a. didactic training in the following areas:

i. radiation physics and instrumentation;

ii. radiation protection;

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

iv. chemistry of by-product material for medical use; and

v. radiation biology; and

b. supervised experience in a nuclear pharmacy involving the following:

i. shipping, receiving, and performing related radiation surveys;

ii. using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure alpha-emitting or beta-emitting radionuclides;

iii. calculating, assaying, and safely preparing dosages for patients or human research subjects;

iv. using administrative controls to avoid mistakes in the administration of by-product material; and

v. using procedures to prevent or minimize contamination and using proper decontamination procedures.

L. Experienced Nuclear Pharmacists. A licensee may apply for and shall receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program, as specified in Subsection K of this Section, before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement, as specified in Subsection K of this Section, and recentness of training, as specified in Subsection O of this Section, to qualify as an authorized nuclear pharmacist.

M. Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a division license on February 20, 1991, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of this Section.

N. Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of Subsection C or D of this Section.

O. Recentness of Training. The training and experience specified in

Subsections A-L of this Section shall have been obtained within the five years preceding the date of application, or the individual shall have had continuing applicable experience since the required training and experience was completed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 18:34 (January 1992), amended LR 24:**.

§777. Quality Management Program

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[See Prior Text in A–A.1.e]

2. that, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

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[See Prior Text in A.3–B.1]

a. a representative sample of patient or human research subject administrations;

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[See Prior Text in B.1.b-H]

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Repealed and repromulgated 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), amended LR 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Nuclear Energy

Chapter 10. Notices, Instructions, and Reports to Workers; Inspections

§1012. Instructions To Workers

A. All individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:

1. kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

2. instructed in the health protection problems associated with exposure to such radioactive material or radiation (including biological risks to an embryo or fetus), in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

3. instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the Louisiana Radiation Protection Regulations (LAC 33:XV) and licenses for the protection of personnel from exposures to radiation or radioactive material;

4. instructed of their responsibility to report promptly to the licensee or registrant any condition that may constitute, lead to, or cause a violation of the Louisiana Radiation Protection Regulations (LAC 33:XV) and licenses or unnecessary exposure to radiation or radioactive material;

5. instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

6. advised as to the radiation exposure reports that workers shall be furnished in accordance with LAC 33:XV.1013.

B. The extent of the instructions required by Subsection A of this Section shall be commensurate with potential radiological health protection problems present in the workplace.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
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 19:1421 (November 1993), LR 22:976 (October 1996), amended LR 24:**.

§1013. Notifications and Reports to Individuals

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[See Prior Text in A–C]

D. When a licensee or registrant is required, in accordance with LAC 33:XV.486, 487, or 488, to report to the division any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or the registrant

shall also provide the individual a written report on his or her exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the division.

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[See Prior Text in E]

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

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 19:1421 (November 1993), LR 22:976 (October 1996), amended LR 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 13. Licensing Requirements for Land Disposal of Radioactive Waste

Subchapter A. General Provisions

§1307. Specific Technical Information

The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this Chapter will be met:

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[See Prior Text in A–M]

N. A description of the facility electronic recordkeeping system as required in LAC 33:XV.1333.J.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
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 23:1139 (September 1997), amended LR 24:**.

Subchapter E. Records, Reports, Tests, and Inspections

§1333. Maintenance of Records, Reports, and Transfers

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[See Prior Text in A–B]

C. Records which shall be maintained in accordance with this Chapter may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

D. Notwithstanding Subsections A – C of this Section, copies of records of the location and the quantity of radioactive wastes contained in the disposal site shall be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor, and other state, local, and federal governmental agencies as designated by the division at the time of license termination.

E. Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date of disposal of the waste, the date that the shipment is received at the disposal facility, a traceable shipment manifest

number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste packages as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or on-site generated materials that are contaminated and are disposed of as contaminated or suspect materials, and any evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified in U.S. Department of Transportation and division regulations. The licensee shall briefly describe any repackaging operations of any of the waste packages included in the shipment, plus any other information required by the division as a license condition. The licensee shall retain these records until the division transfers or terminates the license that authorizes the activities described in this Section.

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[See Prior Text in F]

G. Each licensee authorized to dispose of waste received from other persons, in accordance with this Chapter, shall submit annual reports to the division. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

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[See Prior Text in G.1-1.f]

2. If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those expected in the materials previously viewed as part of the licensing action, the report shall cover this specifically.

H. If there is a conflict between the division's regulations in this Chapter, license condition, or other written division approval or authorization pertaining to the retention period for the same type of record, the longest retention period specified takes precedence.

I. Any transfer of radioactive materials by the licensee is subject to the requirements in LAC 33:XV.340.

J. In addition to the other requirements of this Section, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.

1. The manifest information that shall be electronically stored is:
   a. that required in LAC 33:XV.Chapter 4.Appendix D, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and
   b. that information required in Subsection E of this Section.

2. If specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium, as defined in LAC 33:XV.Chapter 4.Appendix D.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
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 24:**.

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 17. Licensing and Radiation Safety Requirements for Irradiators

§1701. Purpose and Scope

A. This Chapter contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This Chapter also contains radiation safety requirements for operating irradiators. The requirements of this Chapter are in addition to other requirements of these regulations. In particular, the provisions of LAC 33:XV.Chapters 1,3,4, and 10 apply to applications and licenses subject to this Chapter. Nothing in this Chapter relieves the licensee from complying with other applicable federal, state, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

B. The regulations in this Chapter apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Chapter.

C. The regulations in this Chapter do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel, medical radiology or teletherapy, radiography for the irradiation of materials for nondestructive testing purposes, gauging, or open-field, agricultural, irradiations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1703. Definitions

As used in this Chapter, the following definitions apply. Other definitions applicable to this Chapter may be found in LAC 33:XV.Chapters 1 and 2.

Annually—at intervals not to exceed one year.

Doubly Encapsulated Sealed Source—a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

Irradiator—a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type,

but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator Operator—an individual who has successfully completed the training and testing described in LAC 33 XV:1735 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Irradiator Operator Supervisor—an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in LAC 33 XV:1735.

Panoramic Dry-Source-Storage Irradiator—an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic Irradiator—an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic Wet-Source-Storage Irradiator—an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool Irradiator—any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product Conveyor System—a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation Room—a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Sealed Source—any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the by-product material.

Seismic Area—any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater Irradiator—an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1705. License Required

No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for use in an irradiator, except in accordance with a specific license issued by the division, the Nuclear Regulatory Commission, or an agreement state. Specific license application procedures and requirements may be found in LAC 33:XV.Chapter 3.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1707. Start of Construction

An applicant for a license shall not begin construction of a new irradiator prior to the submission to the division of both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this Chapter, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state statute, rules, regulations, and orders issued under the appropriate state statute.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1709. Applications for Exemptions

Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Chapter. The division shall approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1711. Request for Written Statements

Each license is issued with the condition that the licensee shall, at any time before expiration of the license and upon the division's request, submit a written statement to enable the division to determine whether the license should be modified, suspended, or revoked.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1713. Performance Criteria for Sealed Sources

A. Requirements for sealed sources installed after promulgation of this Chapter:

1. shall have been evaluated by the division, the Nuclear Regulatory Commission, or an agreement state in accordance with 10 CFR 32.210;

2. shall be doubly encapsulated;

3. shall use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. shall be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance, if the sources are for use in irradiator pools; and

5. in prototype testing of the sealed source, shall have been leak-tested and found leak-free after each of the tests described in Subsections B–G of this Section.

B. Temperature. The test source shall be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

C. Pressure. The test source shall be twice subjected for at least five minutes to an absolute external pressure of two million newtons per square meter.

D. Impact. A two kilogram steel weight, 2.5 centimeters in diameter, shall be dropped from a height of one meter onto the test source.

E. Vibration. The test source shall be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

F. Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, shall be dropped from a height of one meter onto the test source.

G. Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1715. Access Control

A. Each entrance to a radiation room at a panoramic irradiator shall have

a door or other physical barrier to prevent inadvertent entry of personnel, if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to the shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The control panel lock shall be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers shall not prevent any individual in the radiation room from leaving.

B. In addition, each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

C. A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels shall activate the alarm described in Subsection B of this Section. The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

D. Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources shall be moved from their shielded position. The alarms shall give individuals enough time to leave the room before the sources leave the shielded position.

E. Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

F. Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

G. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators shall also have a sign stating "Grave danger, very high radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

H. If the radiation room of a panoramic irradiator has roof plugs or

other movable shielding, it shall not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

I. Underwater irradiators shall have a personnel access barrier around the pool, which shall be locked to prevent access when the irradiator is not attended. Only operators or facility management shall have access to keys that operate the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an individual who is not necessarily on-site, but who is prepared to respond or summon assistance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1717. Shielding

A. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator shall not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour shall be locked, roped off, or posted.

B. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator shall not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

C. The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded shall not exceed 0.02 millisievert (two mrem) per hour and at five centimeters from the shield shall not exceed 0.2 millisievert (20 mrem) per hour.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1719. Fire Protection

A. The radiation room at a panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

B. The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality,

Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1721. Radiation Monitors

A. Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically. The alarm shall be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this Subsection.

B. Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1723. Control of Source Movement

A. The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room shall require the same key.

B. The console of a panoramic irradiator shall have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

C. The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.

D. Each control for a panoramic irradiator shall be clearly marked as to its function.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1725. Irradiator Pools

A. For licenses initially issued after promulgation of this Chapter, irradiator pools shall either:

1. have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

2. be constructed so that there is a low likelihood of substantial leakage, and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

B. For licenses initially issued after promulgation of this Chapter, irradiator pools shall have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons shall have siphon breakers to prevent the siphoning of pool water.

C. A means shall be provided to replenish water losses from the pool.

D. A visible indicator shall be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

E. Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity such that the sources can be seen clearly.

F. A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

G. If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (two mrem) per hour.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1727. Source Rack Protection

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1729. Power Failures

A. If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources shall automatically return to the shielded position.

B. The lock on the door of the radiation room of a panoramic irradiator shall remain locked in the event of a power failure.

C. During a power failure, the area of any irradiator where sources are located shall be entered only when using an operable and calibrated radiation survey meter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1731. Design Requirements

A. Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of LAC 33:XV.1717. If the irradiator shall use more than 2×10^{17} becquerels (5 million Ci) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

B. Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

C. Pool Integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of LAC 33:XV.1725.B, and that metal components are metallurgically compatible with other components in the pool.

D. Water Handling System. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of LAC 33:XV.1725.E. The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

E. Radiation Monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by LAC 33:XV.1721.A. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under LAC 33:XV.1743.B, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

F. Source Rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power shall not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, shall not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall

review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

G. Access Control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system shall meet the requirements of LAC 33:XV.1717.

H. Fire Protection. For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

I. Source Return. For panoramic irradiators, the licensee shall verify that the source rack shall automatically return to the fully shielded position if power is lost for more than 10 seconds.

J. Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source, such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

K. Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

L. Irradiators whose construction begins after promulgation of this Chapter shall meet the design requirements of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1733. Construction Monitoring and Acceptance Testing

A. Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

B. Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

C. Pool Integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of LAC 33:XV.1725.B.

D. Water Handling System. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

E. Radiation Monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by LAC 33:XV.1721.A. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet the requirements of LAC 33:XV.1743.B. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by LAC 33:XV.1721.A.

F. Source Rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing shall include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in LAC 33:XV.1729 are met for protection of the source rack and the mechanism that moves the rack; testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

G. Access Control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

H. Fire Protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

I. Source Return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

J. Computer Systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system shall operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

K. Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

L. The requirements of this Section shall be met for irradiators whose construction begins after promulgation of this Chapter. The requirements shall be met prior to loading sources.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1735. Training

A. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall be instructed in:

1. the fundamentals of radiation protection applied to irradiators. This shall include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses shall be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

2. the requirements of this Chapter and LAC 33:XV.Chapter 10 that are relevant to the irradiator;

3. the operation of the irradiator;

4. those operating and emergency procedures listed in LAC 33:XV.1737 that the individual is responsible for performing; and

5. case histories of accidents or problems involving irradiators.

B. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

C. Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

D. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review shall include, to the extent appropriate, each of the following:

1. changes in operating and emergency procedures since the last review, if any;

2. changes in regulations and license conditions since the last review if any;

3. reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

4. relevant results of inspections of operator safety performance;

5. relevant results of the facility's inspection and maintenance checks; and

6. a drill to practice an emergency or abnormal event procedure.

E. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

F. Individuals who shall be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in LAC 33:XV.1737 that they are expected to perform or comply with, and their proper response to alarms required in this Chapter. Tests may be oral.

G. Individuals who shall be prepared to respond to alarms required by LAC 33:XV.1715.B and I, 1719.A, 1721.A and B, and 1743.B shall be trained and tested on how to respond. Each individual shall be retested at least annually. Tests may be oral.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1737. Operating and Emergency Procedures

A. The licensee shall have and follow written operating procedures for:

1. operation of the irradiator, including entering and leaving the radiation room;

2. use of personnel dosimeters;

3. surveying the shielding of panoramic irradiators;

4. monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. leak testing of sources;

6. inspection and maintenance checks required by LAC 33:XV.1745;

7. loading, unloading, and repositioning sources, if the operations shall be performed by the licensee; and

8. inspection of movable shielding required by LAC 33:XV.1715.H, if applicable.

B. The licensee shall have and follow emergency or abnormal event procedures appropriate for the irradiator type for:

1. sources stuck in the unshielded position;

2. personnel overexposures;

3. radiation alarms from the product exit portal monitor or pool monitor;

4. detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. low or high water level indicators, abnormal water loss, or leakage from the source storage pool;

6. prolonged loss of electrical power;

7. fire alarms or explosions in the radiation room;

8. alarms indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

9. natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. jamming of automatic conveyor systems.

C. The licensee may revise operating and emergency procedures without division approval only if all of the following conditions are met:

1. the revisions do not reduce the safety of the facility;

2. the revisions are consistent with the outline or summary of procedures submitted with the license application;

3. the revisions have been reviewed and approved by the radiation safety officer; and

4. the users or operators are instructed and tested on the revised procedures before they are put into use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1739. Personnel Monitoring

A. Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor shall be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges in accordance with LAC 33:XV.430.C. Each film badge or TLD shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and TLDs shall be processed at least quarterly.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For

groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this Subsection , a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within ±20 percent of the true radiation dose.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1741. Radiation Surveys

A. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator snall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of irradiators shall be conducted after the sources are loaded, but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

B. If the radiation levels specified in LAC 33:XV.1717 are exceeded, the facility shall be modified to comply with the requirements in LAC 33:XV.1717.

C. Portable radiation survey meters shall be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration shall be done at two points on each scale or, for digital instruments, at one point per decade over the range that shall be used. Portable radiation survey meters shall be of a type that does not saturate and read zero at high radiation dose rates.

D. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations shall not exceed those specified in LAC 33:XV.Chapter 4.Appendix B.Table II, Column 2, or Appendix B.Table III, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure, Effluent Concentrations, Concentrations for Release to Sanitary Sewerage."

E. Before releasing resins for unrestricted use, they shall be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1743. Detection of Leaking Sources

mCi typographic error verified on 10/5/98 Corrected Value = 0.005 mCi

A. Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the division, the Nuclear Regulatory Commission, an agreement state, or a licensing state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source shall not be used until tested. The test shall be capable of detecting the presence of 200 becquerels (0.005 Ci) of radioactive material and shall be performed by a person approved by the division, the Nuclear Regulatory Commission, an agreement state, or a licensing state to perform the test.

B. For pool irradiators, sources shall not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

C. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee that is authorized to perform these functions by the division, the Nuclear Regulatory Commission, an agreement state, or a licensing state. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product shall be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a licensee that is authorized to perform these functions by the division, the Nuclear Regulatory Commission, an agreement state, or a licensing state. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in LAC 33:XV.Chapter 4.Appendix B.Table II, Column 2. The licensee shall report all incidents in accordance with LAC 33:XV.486.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1745. Inspection and Maintenance

A. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. operability of each aspect of the access control system required by LAC 33:XV.1715;

2. functioning of the source position indicator required by LAC 33:XV.1723.B;

3. operability of the radiation monitor for radioactive contamination in pool water, required by LAC 33:XV.1743.B, using a radiation check source, if applicable;

4. operability of the over-pool radiation monitor at underwater irradiators, as required by LAC 33:XV.1721.B;

5. operability of the product exit monitor required by LAC 33:XV.1721.A;

6. operability of the emergency source return control required by LAC 33:XV.1723.C;

7. visual inspection of leak-tightness of systems through which pool water circulates;

8. operability of the heat and smoke detectors and extinguisher system required by LAC 33:XV.1719, without turning extinguishers on;

9. operability of the means of pool water replenishment required by LAC 33:XV.1725.C;

10. operability of the indicators of high and low pool water levels required by LAC 33:XV.1725.D;

11. operability of the intrusion alarm required by LAC 33:XV.1715.I, if applicable;

12. functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

13. condition of the barrier to prevent products from hitting the sources or source mechanism, as required by LAC 33:XV.1727;

14. amount of water added to the pool to determine if the pool is leaking;

15. electrical wiring on required safety systems for radiation damage; and

16. pool water conductivity measurements and analysis, as required by LAC 33:XV.1747.B.

B. Malfunctions and defects found during inspection and maintenance checks shall be repaired within time frames specified in the license or license application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division,

LR 24:**.

§1747. Pool Water Purity

A. Pool water purification systems shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

B. The licensee shall measure the pool water conductivity frequently, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1749. Attendance During Operation

A. Both an irradiator operator and at least one other individual, who is trained as to how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site:

1. whenever the irradiator is operated using an automatic product conveyor system; and

2. whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

B. At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training as to how to respond to alarms described in LAC 33:XV.1735.G shall be on site.

C. At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they shall have received the training described in LAC 33:XV.1735.F and G. Static irradiations may be performed without a person present at the facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1751. Entering and Leaving the Radiation Room

A. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

B. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. visually inspect the entire radiation room to verify that no one else is in it; and

2. activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

C. During a power failure, the area around the pool of an underwater irradiator shall not be entered without using an operable and calibrated radiation survey meter, unless the over-the-pool monitor required by LAC 33:XV.1721.B is operating with backup power.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1753. Irradiation of Explosive or Flammable Materials

A. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the division. Authorization shall not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

B. Irradiation of more than small quantities of flammable material with a flash point below 140°F is prohibited in panoramic irradiators, unless the licensee has received prior written authorization from the division. Authorization shall not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1755. Records and Retention Periods

A. The licensee shall maintain the following records at the irradiator for a three year period:

1. records of each individual's training, tests, and safety reviews provided to meet the requirements of LAC 33:XV.1735.A-D, F, and G until three years after the individual terminates work;

2. records of the annual evaluations of the safety performance of LAC 33:XV.1735.E for three years after the evaluation;

3. a copy of the current operating and emergency procedures required by LAC 33:XV.1737 until superseded or the division terminates the license. Records of the radiation safety officer's review and approval of changes in

procedures, as required by LAC 33:XV.1737.C.3, shall be retained for three years from the date of the change;

4. records of radiation survey meter calibrations required by LAC 33:XV.1741 and pool water conductivity meter calibrations required by LAC 33:XV.1747.B until three years from the date of calibration;

5. records of the results of leak tests required by LAC 33:XV.1743.A and the results of contamination checks required by LAC 33:XV.1743.B for three years from the date of each test;

6. records of inspection and maintenance checks required by LAC 33:XV.1745 for three years;

7. records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed; and

8. records of radiation surveys required by LAC 33:XV.1741 for three years from the date of the survey.

B. The licensee shall maintain the following records at the irradiator for the periods specified:

1. a copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the division terminates the license for documents not superseded;

2. film badge and TLD results required by LAC 33:XV.1739 until the division terminates the license;

3. records of the receipt, transfer, and disposal of all licensed sealed sources as required by LAC 33:XV.104 and 340;

4. records on the design checks required by LAC 33:XV.1731 and the construction control checks as required by LAC 33:XV.1733 until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included; and

5. records related to decommissioning of the irradiator, as required by LAC 33:XV.325.D.7.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.

§1757. Reports

A. In addition to the reporting requirements in other parts of these regulations, the licensee shall report the following events if not reported under other parts of these regulations:

1. source stuck in an unshielded position;

2. any fire or explosion in a radiation room;

3. damage to the source racks;

4. failure of the cable or drive mechanism used to move the source racks;

5. inoperability of the access control system;

6. detection of radiation source by the product exit monitor;

7. detection of radioactive contamination attributable to licensed radioactive material;

8. structural damage to the pool liner or walls;

9. water loss or leakage from the source storage pool greater than the irradiator pool design parameters submitted to the licensee or applicant; and

10. pool water conductivity exceeding 100 microsiemens per centimeter.

B. The report shall include a telephone report within 24 hours, as described in LAC 33:XV.485.A, and a written report within 30 days, as described in LAC 33:XV.485.B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 24:**.