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State of Louisiana

DEPARTMENT OF ENVIRONMENTAL QUALITY
OFFICE OF ENVIRONMENTAL COMPLIANCE

December 21, 2012

Pamela J. Henderson, Deputy Director
Division of Materials Safety and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Ms Henderson:

Enclosed are copies of the final revisions to the Louisiana Department of Environmental Quality rules in the Louisiana Administrative Code, Title 33, Part XV, Radiation Protection. The final regulations are identified by strikeout/underline and correspond to the following equivalent amendments to NRC's regulations.

RATS ID	Title	State Section
1991-3	Standards for Protection Against Radiation	102.Definitions, 332, 399. App. G, 403.Definitions, 406.D, 410, 411, 412, 413, 416, 417, 421, 443, 450, 451, 453, 454, 460, 462, 465, 470, 476, 485, 486, 487, 491, 493, 499.Appendices A, B, C, & D
1991-4	Notification of Incidents	486
1993-1	Decommissioning Recordkeeping and License Termination	102.Definitions, 304, 325, 326, 328, 332, 402, 414, 421, 445, 452, 465, 470, 499.App. D, 550, 701, 702, 703, 704, 707, 709, 710, 712, 713, 715, 717, 720, 721, 725, 729, 731, 735, 736, 737, 742, 743, 744, 745, 750, 753, 754, 763, 765, 766, 767, 770, 771, 775, 777, 1012, 1013, 1307, 1333, 1701
1996-3	Termination or Transfer of Licensed Activities	478

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We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200. These final rules were promulgated November 20, 1993, June 30, 1995, November 20, 1998, and May 20, 2000, respectively, but never submitted to you as final rules.
If you have any questions, please feel free to contact me at (225) 219-3634 or Joe Noble of my staff at (225) 219-3643 or joe.noble@la.gov.

Sincerely,
Judith A. Schuerman

Judith A. Schuerman, Ph.D.
Environmental Scientist Manager
Assessment Division/Radiation Section

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.

* * *

~~*Special Form* either of the following physical forms of licensed material:~~

~~1. The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than 5 millimeters; does not melt, sublime, or ignite in air at a temperature of 1,000°F (538°C); will not shatter or crumble if subjected to the percussion test described in 10 CFR 71.77; and is not dissolved or converted into dispersible form to the extent~~

~~of more than 0.005 percent by weight by immersion for one week in water at 68°F (20°C) or in air at 86°F (30°C).~~

~~2. The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than 5 millimeters, that will retain its contents if subjected to the tests prescribed in 10 CFR 71.77; and that is constructed of materials that do not melt, sublime, or ignite in air at 1,475°F (802°C), and that do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F (20°C) or in air at 86°F (30°C).~~

Special Form Material—radioactive material which satisfies the following:

1. it is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. the piece or capsule has at least one dimension not less than five millimeters (0.197 inch);

3. it satisfies the test requirements of 10 CFR 71.75; and

4. a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4(o) in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this Section applicable at the time of its design or construction.

* * *

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:**

§113. Appeal Procedure, Administrative Review

A. Any person affected by the regulatory actions of the division or administrative authority shall comply with R.S. 30:2024. ~~may request a hearing which shall be held and conducted by the administrative authority or his or her designee. That person shall be admitted as a party to such proceeding.~~

B. Applications to Request a Hearing

1. Any person who alleges that he or she has been aggrieved by the final actions or decision of the division or administrative authority may make application to the administrative authority, in writing, within ~~3~~20 days after the occurrence of the alleged grievance or ~~3~~20 days after the promulgation of any directive, order, decision or other written decision or declaration of the Radiation Protection Division or administrative authority.

* * *

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:**

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 2. Registration of Radiation Machines and Facilities

§201. Purpose and Scope

A. This Chapter provides for the registration of radiation machines and facilities and for the registration of persons providing radiation machine installation, servicing, and/or services.

B. In addition to the requirements of this Chapter, all registrants are subject to the applicable provisions of ~~other chapters of these regulations~~LAC 33:XV.

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:**

§202. Definition

For purposes of this Chapter ~~2 of these regulations,~~ the following definition applies:

Facility ~~means~~ the location at which one or more radiation devices or sources are installed and/or located within one building, vehicle, or under one roof and ~~which~~ are under the same administrative control.

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:**

§203. Exemptions

A. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Chapter, providing the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed 0.5 mRem (5μSv) per hour at 5.0 ~~em~~centimeters from any accessible surface of such equipment,

as per 21 CFR 1020.10(c)(2). The production, testing, or factory servicing of such equipment shall not be exempt.

* * *

C. Domestic television receivers, electron beam welders, computer monitors, domestic microwaves, and electron microscopes are exempt from the requirements of this Chapter.

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:**

§204. Application for Registration of Radiation Machines and Facilities

Each person having a radiation machine or facility not presently registered shall do the following:

~~A~~1. ~~A~~apply for registration of such facility and each radiation machine with the division ~~within 30 days following the effective date of these regulations or thereafter~~ prior to the operation of a radiation machine facility. Application for

registration shall be completed on Form DRC-6 furnished by the division ~~on~~ upon request in writing and shall contain all the information required by the form and accompanying instructions. The registration of the first radiation-producing machine at a facility constitutes registration of the facility itself~~.~~;

~~B~~2. ~~D~~designate on the application form an individual who shall be responsible for radiation protection~~.~~; and

~~C~~3. ~~E~~each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in LAC 33:XV.205.A to his or her radiation machine facility until such person provides satisfactory evidence that he or she has been registered with the division as a provider of services in accordance with LAC 33:XV.205.

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:**

§205. Application for Registration of Servicing and Services

A. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of such services with the division within 30 days ~~following~~after the effective date of this ~~regulation~~Chapter or thereafter prior to furnishing or offering to furnish any such services.

B. Application for registration shall be completed on Form DRC-22 furnished by the division upon request in writing and shall contain all information required by the form and accompanying instructions.

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:**

§206. Issuance of Registration Certificate

A. Upon a determination that an applicant meets the requirements of ~~the regulations~~LAC 33:XV, the ~~secretary~~administrative authority shall issue a "Registration

Certificate for Non-Licensed Sources of Radiation."

B. The division may incorporate in the ~~R~~registration ~~c~~certificate, at the time of the issuance or thereafter by appropriate rule, regulation, or order, such additional requirements, affirmative obligations, and conditions with respect to the registrant's receipt, possession, use, and transfer of sources of radiation as it deems appropriate or necessary.

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:**

§207. Expiration of Registration Certificate

Except as provided by LAC 33:XV.208.B, each registration certificate shall expire at the end of 60 days ~~following~~after notification of expiration by the division.

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:**

§208. Renewal of Registration Certificate

A. Application for renewal of registration shall be filed in accordance with ~~Section 204 of this Chapter~~LAC 33:XV.204.

B. In any case in which a registrant, not less than 30 days prior to the expiration of his or her existing registration certificate, has filed Form DRC-6 application in proper form for renewal, such existing registration certificate shall not expire until the application status has been finally determined by the division.

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:**

§209. Report of Changes

The registrant shall notify the division in writing before making any change ~~which~~that would render the information contained in the application for registration and/or registration certificate no longer accurate.

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:**

§210. Approval Not Implied

No person, in any advertisement, shall refer to the fact that a facility or machine is registered with the division pursuant to the provisions of ~~Section 204 of this Chapter~~LAC 33:XV.204, and no person shall state or imply that any activity under such registration has been approved by the division.

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:**

§211. Assembler and/or Transferor Obligation

A. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this state shall notify the division at ~~90~~15-day intervals of:

1. the name and address of persons who have received these machines;

2. the manufacturer, model, and serial number of each radiation machine transferred; and

3. the date of transfer of each radiation machine.

B. In the case of diagnostic x-ray systems that contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-ray Standard (21 CFR 1020.30[d]) will suffice in lieu of quarterly reports.

~~B~~C. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment,

when properly placed in operation and used, shall meet the requirements of ~~these regulations~~LAC 33:XV.

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:**

§212. Out-of-State Radiation Machines

A. Temporary Use. Whenever any radiation machine is to be brought into Louisiana for any temporary use:

~~1. Whenever any radiation machine is to be brought into Louisiana for any temporary use, the person proposing to bring such machine into the state shall give written notice to the division at least two working days before such machine is to be used in the state. The notice shall include:~~

1. the person proposing to bring such machine into the state shall give written notice to the division at least three working days before such machine is to be used in the state. Additional requirements for work involving industrial radiography

at temporary job sites may be found in LAC 33:XV.Chapter 5. The notice shall include:

a. the type of radiation machine;

b. the nature, duration, and scope of use; and

c. the exact location(s) where the radiation machine is to be used;

~~Additional requirements for work involving industrial radiography at temporary jobsites may be found in Chapter 5.~~

2. ~~I~~if, for a specific case, the ~~two~~three-working-day period would impose an undue hardship on the person, upon written application to the division, permission to proceed sooner may be granted.

* * *

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:**

§213. Modification, Revocation, and Termination of Registration Certificate

A. The terms and conditions of any registration certificate shall be subject to amendment, revision, or modification, or the registration certificate may be suspended or revoked by reason of amendments to the act or by reason of rules, regulations, and orders issued by the administrative authority.

B. Any registration certificate may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the act or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the administrative authority to refuse to grant a registration certificate on an original application, or for violation of, or failure to observe any of, the terms and conditions of the act or of the registration certificate or of any rule, regulation, or order of the administrative authority, including failure to pay assessed fees. Whether a false statement is material shall be determined by the administrative authority.

C. Except in cases of willfulness or those in which the public welfare, interest, or safety requires otherwise, no

registration certificate shall be modified, suspended, or revoked unless, prior to the institution of proceedings thereof, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

D. The division will terminate a registration certificate upon written request by the registrant, provided the registrant no longer possesses the registered device or provided the registrant has rendered the unit permanently incapable of producing radiation. The registrant shall notify the division within 60 days of the final disposition of the x-ray machine.

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:**

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 6. X-Rrays in the Healing Arts

§601. Scope

This Chapter establishes requirements, for which a licensee or registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Chapter are in addition to, and not in substitution for, other applicable provisions of ~~these regulations~~ LAC 33:XV.

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:**

§602. Definitions

~~A.~~ ~~—~~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.

Accessible Surface ~~means~~ the external surface of the enclosure or housing provided by the manufacturer.

~~*Added Filter* the filter added to the inherent filtration.~~

Added Filtration—any filtration that is in addition to the inherent filtration.

Aluminum Equivalent—the thickness of ~~aluminum (~~type 1100 aluminum alloy~~)~~ affording the same attenuation, under specified conditions, as the material in question. ~~(~~The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, ~~and~~ 0.12 percent copper~~)~~.

Assembler—any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide

professional or commercial services.

Attenuation Block—a block or stack, having dimensions 20 ~~em~~centimeters by 20 ~~em~~centimeters by 3.8 ~~em~~centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

Automatic Exposure Control—a device ~~which~~ that automatically controls one or more technique factors in order to obtain~~,~~ at a preselected location~~[s]~~ or locations~~,~~ a required quantity of radiation (see also *Phototimer*). ~~When the word exposure is used in this part to mean one or more irradiations of a person for a healing arts purpose or in a more general sense, it will not be underlined. [See also Phototimer.]~~

Barrier—(See *Protective Barrier.*)~~.~~

Beam Axis—a line from the source ~~of x-rays~~ through the centers of the x-ray fields.

Beam-limiting Device—a device ~~which~~ that provides a means to restrict the dimensions of the x-ray field.

Beam Monitoring System—a system designed to detect and measure the radiation present in the useful beam.

C Arm X-ray System—an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

Cephalometric Device—a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified Components—components of x-ray systems that are subject to the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, promulgated under Public Law 90-602.

Certified System—any x-ray system that has one or more certified component(s).

Changeable Filters—any filter, exclusive of inherent filtration, ~~which~~ that can be removed from the useful ~~x-ray~~ beam through any electronic, mechanical, or physical process.

Coefficient of Variation or "C"—the ratio of the standard deviation to the mean value of a population of observations.

Computed Tomography (CT)—the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

~~*Contact Therapy System* that the x-ray tube port is put in contact with, or within 5 centimeters of, the surface being treated.~~

Contact Therapy System—an x-ray system used for therapy with the x-ray tube port placed in contact with or within five centimeters of the surface being treated.

Control Panel—that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling Curve—the graphical relationship between heat units stored and cooling time.

Dead-man Switch—a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector—(See *Radiation Detector.*)

Diagnostic Source Assembly—the tube housing assembly with a

beam-limiting device attached.

Diagnostic-type ~~Protective~~ Tube Housing ~~—~~a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.

Diagnostic X-ray Imaging System—an assemblage of components for the generation, emission, and reception of x-rays and the transformation, storage, and visual display of the resultant x-ray image.

Diagnostic X-ray System—an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

~~*Direct Scattered Radiation* that radiation which has been deviated in direction only by materials irradiated by the useful beam [See also *Scattered Radiation*].~~

Direct Scattered Radiation—radiation emanating from materials irradiated by the primary beam.

Entrance Exposure Rate—the exposure free in air per unit

time at the point where the center of the useful beam enters the patient.

Equipment—(sSee *X-Ray Equipment.*)

Exposure—the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the Rroentgen.)

~~*Exposure Rate* the Roetgens per unit time at the point where the center of the useful beam enters the patient.~~

Field Emission Equipment—equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter—material placed in the useful beam to ~~attenuate~~ absorb preferentially selected radiations.

Fluoroscopic Imaging Assembly—a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device,

electrical interlocks, ~~(~~if any~~)~~, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal Spot (actual)—the area on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

General Purpose Radiographic X-ray System—any radiographic x-ray system ~~which~~ that, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad Shield—a protective barrier ~~used to cover~~for the testes or ovaries of not less than 0.5 mm lead equivalency.

Half-value Layer ~~*(HVL)*~~—the thickness of specified material ~~which~~ that attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any ~~which~~ that might be present initially in the beam concerned, is deemed to be excluded.

Healing Arts Screening—the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually

ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

HVL—(See *Half-value Layer*.)

Image Intensifier—a device, ~~including~~ installed in its housing, ~~which~~ that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image Receptor—any device, such as a fluorescent screen or radiographic film/screen combination, ~~which~~ that transforms incident x-ray photons either into a visible image or into another form ~~which~~ that can be made into a visible image by further transformations.

Image Receptor Support—for mammographic systems, that part of the system designed to support the image receptor during mammography.

Inherent Filtration—the filtration ~~permanently in~~ of the useful beam~~; it includes the window of the x-ray tube and any permanent tube or source enclosure~~ provided by the permanently installed components of the tube housing assembly.

Irradiation—the exposure of matter to ionizing radiation.

Kilovolts Peak ~~(kVp)~~ (See *Peak Tube Potential*.) ~~.~~

kV—kilovolts.

~~*Kilowatt-second [kWs]* the product of peak kilovolts, amperes and seconds or $[10_3][Kv][Ma][sec]$.~~

Kws—kilowatt second.

Lead Equivalent—the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage Radiation—radiation emanating from ~~a~~the diagnostic or therapeutic source assembly except for:

1. the useful beam; and

2. radiation produced when the exposure switch or timer is not activated.

Leakage Technique Factors—the technique factors associated with the ~~tube housing~~ diagnostic or therapeutic source assembly

~~which~~ that are used in measuring leakage radiation. They are defined as follows:

1. for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs ~~(mAs)~~, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger;

2. for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and

3. for all other ~~equipment~~diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube~~d~~ potential.

Light Field—that area of the intersection of the light beam from the beam-limiting device and one of the sets of planes parallel to and including the plane of the image receptor, whose

perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage Regulation—the difference between the no-load and the load line potentials expressed as a percentage of the load line potential. It is calculated using the following equation:

$$\text{Percent line - voltage regulation} = 100\ \frac{(V_n - V_l)}{V_l}$$

where

V_n = no-load line potential; and

V_l = load line potential.

mA—milliampere.

mAs—milliampere second.

Maximum Line Current—the ~~rms (~~root-mean-square~~)~~ current in the supply line of an x-ray machine operating at its maximum rating.

Mobile X-ray Equipment—(See *X-ray Equipment*).

Operator—an individual who, under the supervision of a practitioner of the healing arts, physically positions patients or animals, determines exposure parameters, and applies the radiation for the diagnostic or therapeutic purposes intended. ~~(~~See the definition of supervision in LAC 33:XV.110.E.~~)~~

Patient—an individual or animal subjected to healing arts examination, diagnosis, or treatment.

Peak Tube Potential (kVp)—the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom—a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Phototimer—a method for controlling radiation exposures to image receptors by measuring the amount of radiation ~~which~~ that reaches a radiation monitoring device~~(s)~~ or devices. The radiation monitoring device~~(s)~~ or devices ~~is~~ are part of an electronic circuit ~~which~~ that controls the duration of time the tube is activated (~~S~~see ~~also~~ *Automatic e~~E~~xposure e~~C~~ontrol*).~~)~~

Portable X-ray Equipment—(See *X-ray Equipment*).

Position Indicating Device (PID)—a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Positive Beam Limitation (PBL)—the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustment.

Primary Beam—(See *Useful Beam*.)~~.~~

Primary Dose Monitoring System—a system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been acquired.

~~*Primary Protective Barrier* [See *Protective Barrier*].~~

Protective Apron—an apron made of radiation ~~attenuating~~ absorbing materials used to reduce radiation exposure.

Protected Area—an area shielded with primary or secondary

protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:

1. ~~two~~ 2 milliroentgens in any one hour; ~~or~~

2. 100 milliroentgens in any seven consecutive days; or

3. 500 milliroentgens in any one year.

Protective Barrier (Primary Protective Barrier)—a barrier of radiation ~~attenuating~~ absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1. *Primary Protective Barrier*—the material, excluding filters, placed in the useful beam, ~~for radiation protection purposes,~~ to ~~reduce the~~ protect anyone other than the patient from radiation exposure.

2. *Secondary Protective Barrier*—a barrier sufficient to ~~attenuate~~ absorb the stray radiation to the required degree.

Protective Glove—a glove made of radiation ~~attenuating~~ absorbing materials used to reduce radiation exposure.

Qualified Expert—an individual who has demonstrated to the satisfaction of the division that ~~he~~ such individual possesses the knowledge, ~~and~~ training, and experience to measure ionizing radiation ~~parameters~~, to evaluate safety techniques, and to advise regarding radiation protection needs.

Quality Control—the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

Radiation Detector—a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Therapy Simulation System—a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph—an image receptor on which the image is created

directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic Imaging System ~~—~~ any system whereby a permanent or ~~semi-permanent~~ temporary image is recorded on an image receptor by the action of ionizing radiation.

~~*Radiological Physicist* a individual who meets one of the following criteria:~~

~~1. is certified in therapeutic radiological physics or radiological physics by the American Board of Radiology or the American Board of Medical Physics; or~~

~~2. has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or nuclear engineering; has had one year of full-time training in therapeutic radiological physics; and has had one year of full-time work experience in a radiotherapy facility where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or~~

~~3. has a bachelor's degree in physics, biophysics, radiological physics, health physics, or nuclear engineering; and has performed full-time radiation physics work for a period of at~~

~~least 10 years prior to October 20, 1987, in the field of therapeutic radiological physics in radiotherapy facilities where the individual's duties involved calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.~~

Rating—the operating limits as specified by the component manufacturer.

Recording—producing a permanent form of an image resulting from x-ray photons ~~(e.g., film, video tape)~~.

Registrant—as used in this Chapter, any person who owns or possesses and administratively controls an x-ray system ~~which~~ that is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in LAC 33:XV.Chapters 1 and/or 2 ~~of these regulations~~ to register with the ~~secretary~~ administrative authority.

~~*Response Time* the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.~~

Scattered Radiation—radiation that, during passage through

matter, has ~~been~~ deviated in direction (see ~~also~~ *Direct Scattered Radiation*).

~~*Screening* testing of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.~~

Secondary Dose Monitoring System—a system that will terminate irradiation in the event of failure of the primary system.

Secondary Protective Barrier—(See *Protective Barrier*.)~~.~~

Shutter—a device attached to the tube housing assembly that can intercept the entire cross sectional area of the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

~~*SID* (See Source-image Receptor Distance).~~

Source—the focal spot of the x-ray tube.

Source-image Receptor Distance (SID)—the distance from the source to the center of the input surface of the image receptor.

Spot Check—a procedure performed to assure that a previous calibration continues to be valid.

Spot ~~f~~Film—a radiograph ~~which is~~ made during a fluoroscopic examination to permanently record conditions ~~which~~ that exist during that fluoroscopic procedure.

Spot Film Device—a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. The term ~~It~~ includes ~~clip-on cassette holders~~ a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD—the distance between the source and the skin entrance plane of the patient.

Stationary X-ray Equipment—(See *X-ray Equipment*.)~~.~~

Stray Radiation—the sum of leakage and scattered radiation.

Technique Factors—the following conditions of operation. ~~They are specified as follows:~~

1. for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. for field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses; ~~and~~

3. ~~for all other equipment~~ for CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA ~~and exposure time in seconds, or the product of tube current and exposure time in mAs.~~, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. for CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5. for all other equipment, peak tube potential in kV,

and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Termination of Irradiation—the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Therapeutic-type Protective Tube Housing—the tube housing with tube installed. It includes high voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tomogram—the depiction of the x-ray attenuation properties of a section through the body.

Traceable to a National Standard—refers to a quantity or a measurement that has been compared to a national standard directly or indirectly through one or more intermediate steps, and all comparisons have been documented.

Tube—an x-ray tube, unless otherwise specified.

Tube Housing Assembly—the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when ~~they~~ such are contained within the tube

housing.

Tube Rating Chart—the set of curves ~~which~~ that specify the rated limits of operation of the tube in terms of the technique factors.

Unprotected Area—any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workloads, exceeds any of the following limits:

1. ~~two~~2 milliroentgens in any one hour;~~—or~~

2. 100 milliroentgens in any seven consecutive days; or

3. 500 milliroentgens in any one year.

Useful Beam ~~or Primary Beam~~—the radiation emanating from the tube housing port or the radiation head and ~~which~~ passes~~ing~~ through the ~~tube housing port and the~~ aperture of the beam-limiting device when the exposure ~~switch or timer is activated~~ controls are in a mode to cause the system to produce radiation.

Variable-aperture Beam-limiting Device—a beam-limiting device ~~which~~ that has the capacity for stepless adjustment of the

x-ray field size at a given SID.

Visible Area—that portion of the input surface of the image receptor over which incident x-ray photons ~~produce~~ are producing a visible image.

Wedge Filter—an added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray Control—a device ~~which~~ that controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray Equipment—an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

1. *Mobile X-ray Equipment*—x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

2. *Portable X-ray Equipment*—x-ray equipment designed to be hand-carried.

3. *Stationary X-ray Equipment*—x-ray equipment ~~which~~ that is installed in a fixed location.

4. *Transportable X-ray Equipment*—x-ray equipment installed in a vehicle or trailer.

X-ray Field—that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image~~d~~ receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray High-voltage Generator—a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray System—an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system

are considered integral parts of the system.

X-ray Subsystem—any combination of two or more components of an x-ray system ~~for which there are requirements specified in this Chapter~~.

X-ray Tube—any electron tube ~~which is~~ designed ~~for the conversion of electrical energy into x-ray energy~~ to be used primarily for the production of x-rays.

~~B. Other definitions applicable to this Chapter may be found in Chapters 1 and 2.~~

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:**

§603. General and Administrative Requirements

~~A. Administrative Responsibilities~~

A. Radiation Safety Requirements. The registrant or

licensee shall be responsible for directing the operation of the x-ray system(s) under his or her administrative control. The registrant or licensee or his or her agent shall assure that the requirements of LAC 33:XV are met in the operation of the x-ray system(s).

~~1. The registrant shall be responsible for directing the operation of the x-ray machines which he has registered with the secretary. He or his agent shall assure that the provisions of these regulations are met in the operation of such x-ray machines.~~

1. An x-ray system that does not meet the provisions of LAC 33:XV shall not be operated for diagnostic or therapeutic purposes if so directed by the division.

~~2. An x-ray machine which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes, if so directed by the division.~~

2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

~~3. Individuals who will be operating x-ray equipment~~

~~shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.~~

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies, for all examinations performed with that system, the following information:

a. patient's body part and anatomical size or body part thickness or age (for pediatrics) versus technique factors to be utilized;

b. type and size of the film or film-screen combination to be used;

c. type and focal distance of the grid to be used, if any;

d. source image receptor distance (SID) to be used (except for dental intraoral radiographs); and

e. type and location of placement of patient shielding (e.g., gonad, etc.) to be used.

4. At the request of the division, the registrant or

licensee of a facility shall create and make available written safety procedures to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

5. Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel, including parents or guardians, required for the medical procedure or training shall be in the room during the radiographic exposure. The following conditions shall be met for those other than the patient being examined:

a. all individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent;

b. the x-ray operator, other professional staff, and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

c. human patients who cannot be removed from the

room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. Any diagnostic information obtained from each exposure shall be reviewed by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

a. exposure of an individual for training, demonstration, or other non-healing arts purposes; and

b. exposure of an individual for the purpose of

healing arts screening without prior written approval of the division.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:

a. mechanical holding devices shall be used when the technique permits. Written safety procedures are required and shall list individual projections where holding devices cannot be utilized;

b. written safety procedures, as required by LAC 33:XV.603.A.8.a, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. the human holder shall be instructed in personal radiation safety and protected as required by LAC 33:XV.603.A.5;

d. no individual shall be used routinely to hold film or patients;

e. in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the

useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;

f. when an animal must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices, such as leaded aprons and gloves, and shall be positioned such that no part of his or her body shall be struck by the useful beam; and

g. each facility must have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized, including, but not limited to:

a. the speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of standard packets for intraoral use in dental radiography;

b. the radiation exposure to the patient shall be the minimum exposure required to produce images of acceptable diagnostic quality;

c. portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation;

d. x-ray systems subject to LAC 33:XV.606 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems;

e. each registrant or licensee, except for veterinarians, covered under this Chapter shall establish written standards for the proper performance of each diagnostic x-ray imaging system under the control of the registrant or licensee, and shall document by routine test record that the system is performing in accordance with these standards (quality control). Copies of this documentation shall be retained for at least six months and be available for inspection by the division. If a test interval is greater than six months, then a copy of the most recent test record shall be retained;

f. if grids are used between the patient and the

image receptor to decrease scatter to the film and improve contrast, the grid shall:

i. be positioned properly, i.e., tube side facing the right direction and grid centered to the central ray; and

ii. if of the focused type, be of the proper focal distance for the SID's being used.

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of LAC 33:XV.410 and 411. In addition, when protective clothing or devices are worn on portions of the body and a personnel monitoring device or devices are required in accordance with LAC 33:XV.431, monitoring devices shall be used as follows:

a. when an apron is worn, at least one such monitoring device shall be worn at the collar outside of the apron;

b. the dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by LAC 33:XV.476. If more than one device is used and a record is made of the data, each dose

shall be identified with the area where the device was worn on the body; and

c. deliberate exposure to an individual's personnel monitoring device is prohibited.

11. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the division. When requesting such approval, that person shall submit the information outlined in Appendix C of this Chapter. If any information submitted to the division becomes invalid or outdated, the division shall be immediately notified. See the definition of *Healing Arts Screening* as defined in LAC 33:XV.602.

~~B. Technique Chart~~

B. X-ray Film Processing Facilities and Practices. Each installation using a radiographic x-ray system and using analog image receptors (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

~~1. In the vicinity of each x-ray system's control panel, a chart will be provided, which specifies for all usual~~

~~examinations which are performed by that system, a listing of information including, but not limited to, the following for each projection within that examination:~~

1. manually developed film:

~~a. patient's anatomical size versus technique factors to be utilized,~~

a. processing tanks for manually developed film shall be constructed of mechanically rigid, corrosion resistant material;

~~b. type and size of the film and/or film-screen combination to be used, where applicable,~~

b. the temperature of solutions in the tanks for manually developed film shall be maintained within the range of 60° to 80°F (16° to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the following time-temperature chart:

TIME-TEMPERATURE CHART

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½

18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

~~c. type and ratio of grid to be used, if any,~~

c. devices shall be utilized for manually developed film that will:

i. indicate the actual temperature of the developer; and

ii. signal the passage of a preset time appropriate to the developing time required.

~~d. source-image receptor distance to be used, and~~

~~e. type and placement of gonad shielding to be used, except in the case of veterinarian use.~~

~~2. For cases in which machine use is restricted to one operator and less than four techniques, the registrant is exempt from the requirements of LAC 33:XV.603.B.1, provided that the information required by LAC 33:XV.603.B.1 is included in written rules and procedures if required in accordance with LAC 33:XV.603.C.~~

2. automatic processors and other closed processing systems:

a. films shall be developed by automatic processors and other closed processing systems in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time*
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21

Developer Temperature		Minimum Immersion Time*
°C	°F	Seconds
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

* Immersion time only, no crossover time included.

b. the specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor in a manner that provides sufficient and legible notice to persons present in these areas.

3. other requirements:

a. pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

b. the darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film;

c. darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed;

d. film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container;

e. film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as

necessary to best assure radiographs of acceptable diagnostic quality;

f. outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed; and

g. film developing solutions shall be prepared in accordance with the directions given by the manufacturer of the chemicals, and shall be maintained in strength by replenishment or renewal so that full development of film is accomplished within the time specified by the manufacturer.

~~C. Written Rules and Procedures~~

~~Written safety procedures and rules, when required in writing by the division, shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the registrant's x-ray system and procedures required to comply with LAC 33:XV.603.H.~~

C. Plans Review

1. Except dedicated mammography radiographic systems and intraoral dental radiographic systems, prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the division for review and approval. The required information is denoted in Appendices A and B of this Chapter.

2. The division may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

3. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in LAC 33:XV.410, LAC 33:XV.416, and LAC 33:XV.421.

~~D. Protection of Patients and Personnel~~

~~1. Except for patients not being examined who cannot be moved out of the unprotected area, only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the unprotected area during the radiographic exposure. Other than the patient being examined:~~

~~a. All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the useful or primary beam.~~

~~b. Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.~~

~~c. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.~~

~~d. When a portion of the body of any professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in Section 410.A of these regulations, additional protective measures shall be employed.~~

~~E. Gonad shielding~~

~~Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct [useful] beam, except for cases in which this would interfere with the diagnostic procedures.~~

~~F. Deliberate Exposures Restricted~~

~~1. Individuals shall not be exposed to the useful beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. Any diagnostic information obtained from each exposure shall be reviewed by a licensed practitioner of the healing arts.~~

~~a. This provision specifically prohibits deliberate exposure for the following purposes:~~

~~i. Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.~~

~~ii. Exposure of an individual for the purpose of healing arts screening without prior written approval of the division.~~

~~2. Any person proposing to conduct a healing arts screening program shall submit the information outlined in Appendix C of this Chapter. If any information submitted to the division becomes invalid or outdated, the Division shall be immediately notified. See the definition of *Screening* is defined in LAC 33:XV.602.A.~~

~~C. Patient Holding and Restraint~~

~~1. When a patient or film must be provided with auxiliary support during a radiographic exposure:~~

~~a. mechanical holding devices shall be used when the technique permits. The safety rules, required by LAC 33:XV.603, shall list individual projections where holding devices cannot be utilized;~~

~~b. written safety procedures, as required by LAC 33:XV.603.C, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;~~

~~c. the human holder shall be protected, as required by LAC 33:XV.603.D.1;~~

~~d. no individual shall be used routinely to hold~~

~~film or patients;~~

~~e. [Reserved];~~

~~f. in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest exposed to the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and~~

~~g. such holding shall be permitted only in very unusual and rare situations when such holding is deemed necessary to obtain diagnostic information [e.g., individuals stressing joints].~~

~~H. Use of Optimum Procedures and Equipment~~

~~1. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include, but not limited to:~~

~~a. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.~~

~~b. The radiation exposure to the patient shall be minimum exposure required to produce images of good diagnostic quality.~~

~~c. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient[s] to a stationary radiographic installation.~~

~~I. Personnel Monitoring~~

~~1. All persons who are associated with the operation of an x-ray system are subject to the occupational dose limits and to the requirements for the determination of the doses which are stated in LAC 33:XV.410 and 411. In addition, the following requirements are made:~~

~~a. When protective clothing or devices are worn on portions of the body and a monitoring device[s] is required in accordance with LAC 33:XV.421, at least one such device shall be utilized as follows:~~

~~i. When a protective apron is worn, the monitoring device shall be worn at the collar outside of the apron.~~

~~ii. The dose to the whole body, based on the maximum dose attributed to any one critical organ [which are the gonads, the blood-forming organs, head and trunk, or lens of the eye], shall be recorded in the reports required by LAC 33:XV.441. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.~~

~~2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~

~~J. Plans Review~~

~~1. Prior to construction or modification, the floor plans and equipment arrangement of all installations [new or modifications of existing installations] utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the division for review and approval. The useful information is denoted in Appendices A and B of this Chapter.~~

~~2. The division may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the review and approval of plans.~~

~~3. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in LAC 33:XV.410, 413 and 414.~~

~~K. Chemicals, Film Processing and Darkrooms See 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 Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:**

§604. General Requirements For All Diagnostic X-Rray Systems

In addition to other requirements of this Chapter, all diagnostic x-ray systems shall meet the following requirements:

~~A. Battery Charge Indicator~~

~~On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.~~

1. Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If leakage technique factors cannot be set on the control panel, then compliance shall be determined by measuring leakage at maximum kVp and an appropriate mAs.

4. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than

the diagnostic source assembly shall not exceed two milliroentgens (0.516 μC/kg) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

5. Beam Quality

a. half-value layer

i. the half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 1 of this Chapter. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 1, linear interpolation or extrapolation may be made.

Table 1

Design Operating Range System	Measured Potential (kVp)	Dental Intraoral Manufactured Before 8/1/74 and on or before 12/1/80	All Other Diagnostic X-ray Half-value Layer (mm of Aluminum)
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5

Design Operating Range System	Measured Potential (kVp)	Dental Intraoral Manufactured Before 8/1/74 and on or before 12/1/80	All Other Diagnostic X-ray Half-value Layer (mm of Aluminum)
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

ii. for capacitor energy storage equipment, compliance with the requirements of LAC 33:XV.604.A.5 shall be determined with the maximum quantity of charge per exposure. This will be deemed to have been met if a mAs of 5-10 has been used.

iii. the required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently between the source and the patient, e.g., a tabletop when the tube is mounted "under the table" and inherent filtration of the tube.

b. filtration controls. For x-ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by LAC 33:XV.604.A.5.a is in the useful beam for the given kVp that has been selected.

6. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

7. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

8. Technique Indicators

a. the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors set prior to the exposure shall be indicated.

b. the requirement of LAC 33:XV.604.A.8.a may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

9. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the federal x-ray equipment performance standard shall be maintained in compliance with applicable requirements of that standard.

~~B. Leakage Radiation from the Diagnostic Source Assembly~~

~~The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in one hour when the x-ray tube is operated at its maximum continuous current at~~

~~its maximum voltage. Compliance shall be determined by measurements over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~C. Beam Quality~~

~~1. Half-Value Layer~~

~~a. The half-value layer [HVL] of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.~~

~~TABLE I~~

~~Design Operating Range [kilovolts peak]~~	~~Measured Potential [kilovolts peak]~~	~~Half-Value Layer [millimeters of aluminum~~
~~Below 50~~	~~30~~	~~0.3~~
	~~40~~	~~0.4~~
	~~49~~	~~0.5~~

50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

b. The TABLE I HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Operating Voltage [kVp]	Total Filtration [inherent plus added] [millimeters aluminum equivalent]

~~Below 50~~	~~0.5 millimeters~~
~~50 - 70~~	~~1.5 millimeters~~
~~Above 70~~	~~2.5 millimeters~~

~~c. Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.~~

~~d. For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.~~

~~e. The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient, e.g., a tabletop when the tube is mounted ''under the table'' and inherent filtration of the tube.~~

~~2. Filtration Controls~~

~~For x-ray systems installed after April 20, 1977, which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter[s] which will prevent an exposure unless the minimum required amount of filtration for the given kVp which has been selected [Table I~~

~~or II above] is in the useful beam.~~

~~D. Multiple Tubes~~

~~Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be on the x-ray control.~~

~~E. Mechanical Support of Tube Head~~

~~The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.~~

~~F. Technique Indicators~~

~~1. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.~~

~~2. On equipment not having technique factors indicated numerically, permanent markings shall indicate the selected~~

~~technique factors.~~

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:**

§605. Fluoroscopic X-Rray Systems

All fluoroscopic x-ray systems shall be image intensified and meet the following requirements:

~~A~~1. Limitation of Useful Beam

~~1. The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.~~

a. primary barrier

i. the fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

ii. the x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.

b. x-ray field

i. neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. In addition, the following requirements apply:

(a). a means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

(b). all equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless

adjustment shall provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters or less;

(c). for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

(d). compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor; and

(e). for uncertified image intensified fluoroscopic equipment with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

ii. spot-film devices that are certified components shall meet the following additional requirements:

(a). means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film;

(b). it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

(c). the center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

(d). on spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided

to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

~~2. The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.~~

2. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

~~3. No new installation or modification of existing equipment shall incorporate fluoroscopy without image intensification.~~

3. Exposure Rate Limits

a. entrance exposure rate allowable limits

i. equipment with automatic exposure rate control. Fluoroscopic equipment provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

(a). during recording of fluoroscopic images; or

(b). when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of five roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be provided only by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

ii. equipment without automatic exposure rate control. Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an

exposure rate in excess of five roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

(a). during recording of fluoroscopic images; or

(b). when an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

iii. compliance with the requirements of LAC 33:XV.605.A.3 shall be determined as follows:

(a). if the source is below the x-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;

(b). if the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of

measurement;

(c). in a C-arm or L-U arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(d). in a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the center line of the x-ray table; and

(e). protective attenuating material equivalent to three millimeters of lead shall be placed between the point of measurement of entrance exposure rate and the input surface of the image receptor.

b. periodic measurement of entrance exposure rates shall be performed by a qualified expert for both maximum and typical values, as follows:

i. such measurements shall be made at installation, annually thereafter or after any maintenance of the system that might affect the exposure rate;

ii. results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope. The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

iii. conditions of periodic measurement of maximum entrance exposure rate are as follows:

(a). the measurement shall be made under the conditions that satisfy the requirements of LAC 33:XV.605.A.3.a.iii;

(b). the kVp, mA, and/or other selectable parameters shall be adjusted to those settings that

give the maximum entrance exposure rate; and

(c). the x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system; and

iv. conditions of periodic measurement of typical entrance rate are as follows:

(a). the measurement shall be made under the conditions that satisfy the requirements of LAC 33:XV.605.A.3.a.iii;

(b). the kVp and mA shall be typical of clinical use of the x-ray system; and

(c). the x-ray system or systems that incorporate automatic exposure rate control shall have an appropriate phantom placed in the useful beam to produce a mA and/or kV typical of the use of the x-ray system.

~~4. Limitation to the Imaging Surface~~

4. Barrier Transmitted Radiation Rate Limits

~~a. Fluoroscopy and Spot-Filming without Image Intensification. The x-ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot-filming procedures.~~

a. the exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed two milliroentgens (0.516 μC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

~~b. Image-Intensified Fluoroscopy and Spot-Filming~~

b. measuring compliance of barrier transmission

~~i. During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.~~

i. the exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

~~ii. Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image receptor, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.~~

ii. if the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

iii. if the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

iv. movable grids and compression devices

shall be removed from the useful beam during the measurement.

~~c. Spot-Film Device. In addition to other requirements of this section for new equipment installed after April 20,1977:~~

~~i. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.~~

~~ii. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than 5 cm by 5 cm.~~

~~iii. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.~~

5. Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be

continuously indicated.

6. Source-to-skin Distance. The SSD shall not be less than:

a. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

b. 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

c. 30 centimeters on all mobile fluoroscopes; and

d. 20 centimeters for all mobile fluoroscopes used for specific surgical procedures. The written safety procedures or user's operating manual must provide precautionary measures to be taken during the use of this type of fluoroscope. If removable, the appropriate spacer shall be replaced after the specific surgical procedure is complete.

7. Fluoroscopic Timer

a. a means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five

minutes without resetting.

b. a signal audible to the fluoroscopist, or the appropriate operator, shall indicate the completion of any preset cumulative on-timer, or if no audible signal is provided, the exposure shall terminate until the cumulative timer is manually reset at the console. Such signal shall either continue to sound while x-rays are produced or shall sound for at least five seconds, whichever is less, until the timing device is reset.

8. Control of Scattered Radiation

a. fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

b. equipment configuration when combined with procedures utilized shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

i. is at least 120 centimeters from the center of the useful beam; or

ii. the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in LAC 33:XV.603.A.5.

c. upon application to the administrative authority with adequate justification, exemptions to LAC 33:XV.605.A.8.b may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the division shall not permit such exemption.

9. Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of LAC 33:XV.606.D when operating in the spot film mode.

10. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the

requirements of LAC 33:XV.605.A.1, 3, 4, and 7, provided that:

a. such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods when the system is producing x-rays; and

b. systems that do not meet the requirements of LAC 33:XV.605.A.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

~~B. Activation of the Fluoroscopic Tube~~

~~X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure[s] at any time, but means may be provided to permit completion of any single exposure of the series in process.~~

~~C. Exposure Rate Limits~~

~~1. Entrance Exposure Rate Allowable Limits~~

~~a. Except as provided in LAC 33:XV.605.C.1.b,c and d., the exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 Roentgens per minute, except during recording of fluoroscopic images or when provided with optional high level control.~~

~~b. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five Roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.~~

~~i. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use.~~

~~ii. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

~~c. Addition to the other requirements of LAC 33:XV.605, any new equipment installed after April 20, 1977, which does not incorporate an automatic exposure control [e.g., automatic brightness control or ionization chamber control] shall~~

~~not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five Roentgens per minute at the point where the center of the useful beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.~~

~~d. Notwithstanding the provisions of LAC 33:XV.605.C.1.a, equipment installed before April 20, 1977, shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens per minute at the point where the center of the useful beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.~~

~~e. Measuring Compliance of Entrance Exposure Rate Limits. Compliance with LAC 33:XV.605.C shall be determined as follows:~~

~~i. Movable grids and compression devices shall be removed from the useful beam during the measurement.~~

~~ii. If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.~~

~~iii. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.~~

~~iv. In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.~~

~~f. Periodic Measurement of Entrance Exposure Rate Limits.~~

~~i. Periodic measurements of the exposure rate shall be made. An adequate period for such measurements shall be annually and after any maintenance of the system which might affect the exposure rate.~~

~~ii. Results of these measurements shall be posted where any fluoroscopist may have ready access to them while using that fluoroscope. Results of the measurements shall include the maximum possible R/minute, as well as the physical factors used to determine all data; the name of the person performing the measurements; and the date the measurements were performed.~~

~~iii. Monitoring devices [e.g., commercially available film badges, thermoluminescent dosimeters, or low energy dosimeters] may be used to perform the test, provided the measurements are made as noted in the following subdivision [iv].~~

~~iv. Conditions of Measurement.~~

~~(a). The measurement shall be made under the conditions that satisfy the requirements of LAC 33:XV.605.C.1.e;~~

~~(b). The kVp shall be the peak kV that the x-ray system is capable of producing;~~

~~(c). The high level control, if present, shall not be activated;~~

~~(d). The x-ray system[s] that incorporates automatic exposure control [automatic brightness control, etc.] shall have sufficient material [e.g., lead or lead equivalence] placed in the useful beam to produce the maximum radiation output of the x-ray system; and~~

~~(e). The x-ray system[s] that does not incorporate automatic exposure control shall utilize the maximum~~

~~milliamperage of the x-ray system. Materials [e.g., an attenuation block] should be placed in the useful beam to protect the imaging system.~~

~~D. Radiation Transmitted through Barrier Rate Limits~~

~~1. The exposure rate resulting from transmission through the primary protective barrier with an attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.~~

~~2. Measuring Compliance of Barrier Transmission~~

~~a. The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

~~b. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above~~

~~the tabletop.~~

~~c. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.~~

~~d. Movable grids and compression devices shall be removed from the useful beam during the measurement.~~

~~e. The attenuation block shall be positioned in the useful beam between the point of measurement of entrance exposure rate and the input surface of the fluoroscopic imaging assembly, and the attentuation block shall be 10 centimeters from the point of entrance exposure rate measurement.~~

~~E. Indication of Potential and Current~~

~~During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.~~

~~F. Source-Skin Distance.~~

~~The source-skin distance shall not be less than:~~

~~1. 38 centimeters on stationary fluoroscopes installed after April 20, 1977.~~

~~2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to April 20, 1977,~~

~~3. 30 centimeters on all mobile fluoroscopes, or~~

~~4. 20 centimeters for image intensified fluoroscopes used for specific surgical application. The user's operating manual must provide precautionary measures to be adhered to during the use of such devices.~~

~~G. Fluoroscopic Timer~~

~~1. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube.~~

~~2. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.~~

~~3. A signal audible to the fluoroscopist, or the appropriate operator, shall indicate the completion of any preset cumulative on-time or, if no audible signal is provided, the exposure shall terminate until the cumulative timer is manually~~

~~reset at the console. Such signal shall either continue to sound while x-rays are produced or shall sound for at least five seconds, whichever is less, until the timing device is reset.~~

~~H. Mobile Fluoroscopes~~

~~In addition to the other requirements of LAC 33:XV.605, mobile fluoroscopes shall provide image intensification.~~

~~I. Control of Scattered Radiation~~

~~1. Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall not be less than 0.25 mm lead equivalent.~~

~~2. Equipment configuration, when combined with procedures utilized, shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:~~

~~a. is at least 120 cm from the center of the~~

~~useful beam; or~~

~~b. the radiation has passed through not less than 0.25 mm lead equivalent material [e.g., drapes, Bucky-slot cover, sliding or folding panel, or self supporting curtains] in addition to any lead equivalency provided by the protective apron referred to in LAC 33:XV.603.D.1.~~

~~3. Upon application to the secretary with adequate justification, exceptions to LAC 33:XV.605.I.2 may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.~~

~~J. Radiation Therapy Simulation System~~

~~If remote control operation is utilized, radiation therapy simulation systems shall be exempt from the requirements of LAC 33:XV.605.~~

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:**

§606. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, ~~Pediatric~~ or ~~Veterinarian~~ Computed Tomography X-ray Systems

A. Beam Limitation. The useful beam shall be limited to the area of clinical interest. This requirement shall be deemed to have been met if a positive beam-limiting device has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

~~1. The x-ray field in the plane of the image receptor shall not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.~~

1. General Purpose Stationary and Mobile X-ray Systems, Including Veterinary Systems Installed after February 21, 1991. These systems shall meet the following requirements:

a. a means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray

field;

b. a method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam; and

c. the division may grant an exemption on noncertified x-ray systems to LAC 33:XV.606.A.1.a and b provided the registrant or licensee makes a written application for such exemption and in that application:

i. demonstrates that it is impractical to comply with LAC 33:XV.606.A.1.a and b; and

ii. the purposes of LAC 33:XV.606.A.1.a and b will be met by other methods.

~~2. The beam size shall be the smallest available to obtain the needed diagnostic information.~~

2. Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of LAC 33:XV.606.A.1, stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

a. a method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

b. the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

c. indication of the field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

~~3. Equipment such as fixed-apertures, adjustable~~

~~collimators, field-defining lights or centering lights or devices shall be provided so that the requirements of LAC 33:XV.606.A.1 and 2 can be met.~~

3. X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

~~a. For equipment installed, purchased or transferred after April 20, 1977, or manufactured after July 31, 1974, the requirements of LAC 33:XV.606.A.3 shall be met by the use of stepless adjustable collimators and field defining lights or automatic collimators. Stationary x-ray systems designed or used with only one image receptor size at a fixed SID are exempt from this requirement.~~

~~b. Adjustable collimators shall be provided as a means for stepless adjustment of the size of the x-ray field. A~~

~~light field defining the perimeter of the x-ray field shall be provided such that any one dimension of the x-ray field shall not be greater than the corresponding dimension of the visually defined field by more than two percent of the distance from source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.~~

~~4. Except as otherwise provided in LAC 33:XV.606.A.5, evidence of compliance with LAC 33:XV.606.A.1 and 3 above shall be shown on each radiograph taken, either by imaging part of the collimator on the radiograph or by imaging collimator nubs or pointers.~~

4. Systems Designed for or Provided With Special Attachments for Mammography. Radiographic systems designed only for mammography, and general purpose radiographic systems when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two percent of the SID. This requirement can be met with a system that performs as prescribed in LAC 33:XV.606.A.5.c.

When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in LAC 33:XV.606.A.5.c.i and ii shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

~~5. The following x-ray systems and techniques are exempt from the requirements of LAC 33:XV.606.A.4:~~

5. X-ray Systems Other Than Those Described in LAC 33:XV.606.A.1, 2, 3, and 4, and Veterinary Systems Prior to February 21, 1991. These systems shall meet the following requirements:

~~a. X-ray systems which utilize stepless adjustable collimators and field defining lights.~~

a. a means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is

perpendicular to the plane of the image receptor;

~~b. X-ray techniques which utilize positive beam limitation.~~

b. a means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor; and

~~c. Stationary x-ray systems designed or used with only one image receptor size at a fixed SID.~~

c. LAC 33:XV.606.A.5.a and b may be met with a system that meets the requirements for a general purpose x-ray system as specified in LAC 33:XV.606.A.1 or, when alignment means are also provided, may be met with either:

i. an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID

for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

ii. a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

~~d. X-ray techniques that require the plane of the image receptor to be oblique to the x-ray beam axis.~~

~~e. X-ray systems or techniques designated as exempt from the requirements of LAC 33:XV.606.A.4 by the secretary in accordance with LAC 33:XV.103.A of these regulations.~~

B. Radiation Exposure Control Devices

~~1. Timers~~

1. Exposure Initiation. A means shall be provided to initiate the radiation exposure by a positive action on the part

of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such a positive action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

~~Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition,~~

~~a. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.~~

~~b. It shall not be possible to make an exposure when the timer is set to a zero or \\off'' position if either position is provided.~~

2. ~~X-ray Control (exposure switch)~~ Exposure Termination

a. manual exposure control. An x-ray exposure ~~A~~ control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman"

switch) except for:

i. exposures of one-half second or less~~,~~; or

ii. during serial radiography when means shall be provided to permit completion of any single exposure of the series in process~~.~~;

~~b. Each x-ray control shall be located in such a way as to meet the following criteria:~~

b. automatic exposure control. When an automatic exposure control is provided:

~~i. the exposure switch shall be operated in a protected area and the operator shall remain in that protected area during the entire exposure.~~

i. indication shall be made on the control panel when this mode of operation is selected;

~~ii. the operator's protected area shall provide means to view the patient during the x-ray procedure.~~

ii. if the x-ray tube potential is equal to

or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

~~iii. for mobile and portable x-ray systems used to make an exposure[s] of only one patient at the use location, such systems shall meet the requirement of LAC 33:XV.606.B.2.b.i or be provided with a method of control which will permit the operator to be at least 12 feet from the tubehead assembly and patient during an exposure.~~

iii. the minimum exposure time for all equipment other than that specified in LAC 33:XV.606.B.2.b.ii shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

~~iv. The x-ray control shall provide visual or audible indication observable at or from the operator's protected position whenever x-rays are produced.~~

iv. either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except that when the x-ray tube potential is

less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

v. a visible signal shall indicate when an exposure has been terminated at the limits required, and manual resetting shall be required before further automatically timed exposures can be made.

~~3. Automatic Exposure Controls [phototimers]. When an automatic exposure control is provided:~~

3. Exposure Indication. The x-ray exposure control shall provide visual or audible indication of x-ray production observable at or from the operator's protected position whenever x-rays are produced.

~~a. Indication shall be made on the control panel when this mode of operation is selected;~~

~~b. When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;~~

~~c. The minimum exposure time for all equipment other than that specified in LAC 33:XV.606.B.3.b shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;~~

~~d. Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and~~

~~e. A visible signal shall indicate when an exposure has been terminated at the limits described in LAC 33:XV.606.B.3.d above and manual resetting shall be required before further automatically timed exposures can be made.~~

~~4. [Reserved]~~

4. Exposure Duration (Timer) Reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to 10 percent of the average exposure time (T), when four timer tests are performed:

$$(T_{max} - T_{max}) \leq 0.1T$$

~~5. Reproducibility.~~

~~When four timer tests are performed at identical timer settings equal to 0.5 seconds or less, the average time period [T] shall be greater than five times the difference between the maximum period [T_{max}] and the minimum period [T_{min}] in accordance with the formula:~~

~~$\bar{T} > 5 [T_{max} - T_{min}]$~~

5. Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

6. Operator Protection Except for Veterinary Systems and Panoramic Dental Systems. The following requirements shall be met:

a. stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area

during the entire exposure; and

b. mobile and portable x-ray systems that are:

i. used continuously for more than one week in the same location, e.g., a room or suite, shall meet the requirements of LAC 33:XV.606.B.2.b.i; and

ii. used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet (two meters) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 12 feet (3.7 meters) from the tube housing assembly during the exposure.

7. Operator Protection for Veterinary Systems and Panoramic Dental Systems. All stationary, mobile, or portable x-ray systems used for veterinary work shall be provided with either a 6.5 foot (two meters) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be least 12 feet (3.7 meters) from the tube housing assembly during exposures.

~~c. Source-Skin or Receptor Distance.~~

C. Source-to-skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to be equal to or greater than 30 centimeters.

~~1. Limitation~~

~~All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to not less than 30 centimeters. This is considered to have been met when the collimator or cone provides the required limits.~~

~~2. [Reserved]~~

D. Exposure Reproducibility~~The exposure produced shall be reproducible to within the following criteria:~~. When all technique factors are held constant, including control panel selections associated with automatic exposure control (phototiming) systems, the coefficient of variation of exposure for both manual and phototimed systems shall not exceed ~~0.10~~0.05. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors ~~are made~~, ~~the value of the average exposure [E] is greater than five times the difference between the maximum exposure [E_{max}] and the minimum~~

~~exposure [E_{min}] in accordance with the formula:~~

~~$\bar{E} > 5\ [E_{max} - E_{min}]$~~

the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) shall be less than or equal to 10 percent of the average exposure (E):

$$(E_{max} - E_{max}) \leq 0.1\ E$$

~~E. Standby Radiation from Capacitor Energy Storage Equipment.~~

~~Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.~~

E. Radiation From Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 μC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly,

with the beam-limiting device fully open.

F. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value.

G. Linearity, Uncertified X-ray Systems Only. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

1. Equipment Having Independent Selection of X-ray Tube Current (mA). The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs or mR/mAs) obtained at any two tube current settings shall not differ by more than 0.10 times their sum. This is:

$$(X_1 - X_2) \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

2. Equipment Having a Combined X-ray Tube Current Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs or mR/mAs) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$(X_1 - X_2) \leq 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

3. Measuring Compliance. Determination of compliance shall be based on four exposures, of no less than 0.05 seconds each, taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

H. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more

certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s):

1. Linearity. When the equipment allows for a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average mR/mAs (C/kg/mAs) values obtained at each of two consecutive tube current settings.

2. Beam Limitation for Stationary and Mobile General Purpose X-ray Systems. The following requirements apply:

a. there shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field

size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters; and

b. when a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of LAC 33:XV.606.A.1 and 606.H.2.

4. Beam Limitation and Alignment on Stationary General Purpose X-ray Systems. For stationary, general purpose x-ray systems that contain a tube housing assembly, an x-ray control, and for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c), the following requirements apply:

a. positive beam limitation (PBL) shall be provided whenever all the following conditions are met:

i. the image receptor is inserted into a permanently mounted cassette holder;

ii. the image receptor length and width are each less than 50 centimeters;

iii. the x-ray beam axis is within ±3 degrees of vertical, and the SID is 90 centimeters to 130 centimeters inclusive, or the x-ray beam axis is within ±3 degrees of horizontal, and the SID is 90 centimeters to 205 centimeters inclusive;

iv. the x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees;

v. neither tomographic nor stereoscopic radiography is being performed; and

vi. the PBL system has not been intentionally overridden. This override provision is subject to LAC 33:XV.606.H.4.c;

b. positive beam limitation (PBL) shall prevent the production of x-rays when:

i. either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by LAC 33:XV.606.H.4.e, from the corresponding image receptor dimensions by more than three percent of the SID; or

ii. the sum of the length and width differences as stated in LAC 33:XV.606.H.4.b.i without regard to sign exceeds four percent of the SID;

c. if a means of overriding the positive beam limitation (PBL) system exists, that means shall meet the following criteria:

i. the means of overriding the PBL system shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

ii. if in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator, the means for overriding the PBL system:

(a). shall require that a key be utilized to defeat the PBL;

(b). shall require that the key remain in place during the entire time the PBL system is overridden; and

(c). shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION

SYSTEM FAILURE

d. compliance with LAC 33:XV.606.H.4.b shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of LAC 33:XV.606.H.4.a are met. Compliance shall be determined no sooner than five seconds after insertion of the image receptor;

e. the positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters; and

f. the positive beam limitation system shall be

designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in LAC 33:XV.606.H.4.b, then any change of image receptor size or SID must cause the automatic return.

5. Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978, that are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

I. Tube Stands for Portable X-ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held

during exposures.

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:**

§607. Intraoral Dental Radiographic Systems

In addition to the provisions of LAC 33:XV.603 and 604, the requirements of this Section apply to x-ray equipment and associated facilities used for dental radiography. ~~Criteria~~ Requirements for extraoral dental radiographic systems are covered in LAC 33:XV.603 and 606.

~~A~~1. Source-to-~~S~~skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than ~~:~~18 centimeters.

~~1. 18 centimeters, if operable at or above 50 kilovolts peak, or~~

~~2. 10 centimeters, if not operable at or above 50 kilovolts peak.~~

~~B~~2. Field Limitation. The following requirements shall be met:

~~1~~a. ~~R~~radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray ~~beam such that:~~field such that the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters;

~~a. If the minimum source-skin distance [SSD] is 18 centimeters or more, the x-ray field at the minimum SSD shall be contained in a circle having a diameter of no more than 7 centimeters; and~~

~~b. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.~~

b. an opened-ended, shielded PID (position-indicating device) shall be used. The shielding shall be

equivalent to the requirements of LAC 33:XV.604.A.3; and

c. the operator shall position the end of the PID as close as practicable to the skin of the patient.

3. Radiation Exposure Control for Certified and Noncertified Systems. The following requirements shall be met:

a. exposure initiation

i. means shall be provided to initiate the radiation exposure by a positive action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such a positive action; and

ii. it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided;

b. exposure termination

i. means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or preset radiation exposure to the image receptor;

ii. an x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half second or less; and

iii. termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero";

c. exposure indication. The x-ray control shall provide visual or audible indication observable at or from the operator's protected position whenever x-rays are produced;

d. exposure duration (timer) reproducibility. With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to 10 percent of the average time (T), when four timing tests are performed:

$$(T_{max} - T_{min}) \leq 0.10\ T$$

e. exposure control location and operator protection. Each x-ray control shall be located in such a way as to meet the following requirements:

i. the intraoral dental x-ray systems shall be operated from a protected area and shall be provided with either a protective barrier at least 6.5 feet (2.0 m) high for operator protection or means to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly while making exposures; and

ii. the operator's protected area shall provide means to view the patient during the x-ray procedure.

4. Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made within a period of one hour at identical technique factors, the difference between the maximum exposure value (E_{max}) and the minimum exposure value (E_{min}) shall be less than or equal to 10 percent of the average exposure (E):

$$(E_{max} - E_{min}) \leq 0.10 E$$

5. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential

within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

6. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specification the deviation shall not exceed 10 percent of the indicated value.

7. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

8. Administrative controls include the following:

a. patient and film holding devices shall be used when the techniques permit;

b. the tube housing and the PID shall not be hand-held during an exposure;

c. the x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of LAC 33:XV.607.A.2.a; and

d. dental fluoroscopy without image intensification shall not be used.

~~c. Timers~~

~~Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition,~~

~~1. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero.~~

~~2. It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.~~

~~3. [Reserved]~~

~~4. Reproducibility~~

~~When four timer tests are performed at identical timer settings equal to 5 seconds or less, the average time period [T] shall be greater than five times the difference between the maximum period [T_{max}] and the minimum period [T_{min}] in accordance with the formula:~~

$$\bar{T} > 5\,[T_{max} - T_{min}]$$

~~D. X-Ray Control [Exposure Switch].~~

~~1. The exposure switch shall be of the dead-man type.~~

~~2. The x-ray control shall provide visual or audible indication at the operator's position whenever x-rays are produced.~~

~~3. The control switch shall be permanently mounted in a protected area [e.g., corridor outside the room] so that the operator is required to remain in that protected area during the entire exposure.~~

~~4. The operator's protected area shall provide means to view the patient during the x-ray procedure.~~

~~3. The x-ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in LAC 33:XV.607.B.1.~~

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:**

§608. Therapeutic X-Rray ~~Installations~~ Systems of ~~(1~~Less ~~t~~Than 1 MeV~~)~~

A. Equipment Requirements

1. Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation ~~in any direction~~ shall not exceed the value specified at the distance specified for the classification of that x-ray system~~.~~, as follows:

a. ~~c~~contact therapy systems~~:. the 1~~ Leakage radiation shall not exceed 100 ~~mR/hr~~ milliroentgens (25.8 μC/kg) per hour at ~~5~~ five centimeters from the surface of the tube

housing~~.~~ assembly;

b. 0-150 kVp systems~~which~~. Systems that were manufactured or installed prior to April 20, 1977~~:~~, shall have a ~~the~~ leakage radiation ~~shall~~that does not exceed ~~1~~one ~~R~~roentgen (0.258 mC/kg) in ~~1~~one hour at ~~1~~one meter from the source~~.~~;

c. 0-150 kVp systems~~which are~~. Systems manufactured on or after April 20, 1977~~:~~,shall have a ~~the~~ leakage radiation ~~shall~~ that does not exceed ~~100 mR~~ 100 milliroentgens (25.8 μC/kg) in ~~1~~one hour at ~~1~~one meter from the source~~.~~; and

d. 151-~~500~~999 kVp systems~~:~~. ~~the 1~~Leakage radiation shall not exceed ~~1~~one ~~R~~roentgen (0.258 mC/kg) in ~~1~~one hour at ~~1~~one meter from the source, except that systems that operate in excess of 500 kVp may have a leakage radiation at one meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

~~e. 501 to 1000 kVp systems: the leakage radiation at one meter from the source shall not exceed 0.1 percent of the useful beam exposure rate at 1 meter from the source.~~

2. ~~Collimation.~~Permanent Beam-limiting Devices. Permanent fixed diaphragms or cones used for ~~collimating~~ limiting

the useful beam shall provide the same or a higher degree of protection ~~than that~~ as required ~~by~~for the tube housing assembly.

3. Removable and Adjustable Beam-~~L~~limiting Devices. These devices shall meet the following requirements:

a. ~~R~~removable beam-limiting devices ~~(diaphragms, cones, etc.)~~ shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the ~~original x-ray~~ useful beam at the maximum kilovoltage and maximum treatment filter. The requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient;

b. ~~A~~adjustable beam-limiting devices installed after April 20, 1977, shall meet the ~~criteria~~ requirements of LAC 33:XV.608.A.3.a ~~above.~~; and

c. ~~A~~adjustable beam-limiting devices installed before April 20, 1977, shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than five percent of the ~~original x-ray~~ useful beam at the maximum kilovoltage and maximum treatment filter.

4. Filtration. The filter system shall be so designed

that~~:~~ it meets the following requirements:

a. the ~~F~~filters cannot be accidentally displaced ~~from the useful beam~~ at any possible tube orientation~~.~~;

b. ~~E~~each filter is marked as to its material of construction and its thickness ~~or wedge angle for wedges~~. For wedge filters, the wedge angle ~~The filters shall be individually distinguishable.~~ shall appear on the wedge or wedge tray;

c. ~~I~~it shall be possible for the operator to determine the presence or absence of each filter and the ~~orientation~~ operation of each wedge filter in the useful beam when ~~he~~ the operator is at his or her position at the control panel either by display at the control panel or by direct observation~~.~~; and

d. ~~The filters and~~the radiation at five centimeters from the filter insertion slot opening ~~shall be so designed that the radiation at 5 cm from the filter insertion slot opening~~ does not exceed 30 ~~R~~roentgens (7.74 mC/kg) per hour under ~~all~~any operating conditions~~.~~

~~e. Each machine equipped with a beryllium or other low filtration window shall be clearly labeled as such upon~~

~~the tube head housing and upon the control panel.~~

5. Tube ~~Housing~~ Immobilization. The tube housing assembly shall be capable of being immobilized ~~during stationary treatments~~ for stationary treatments.

6. ~~Tube Housing Marking~~ Focal ~~s~~Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within ~~5~~five millimeters, and such marking shall be readily accessible for use during calibration procedures.

7. ~~Contact Therapy Tube Housing.~~ Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 ~~mm~~millimeter lead equivalency at 100 kVp that ~~shall~~ can be positioned over the entire useful beam exit port during periods when the beam is not in use.

8. Beam Monitor System. ~~New equipment~~ Systems of greater than 150 kVp ~~installed~~ manufactured after April 20, 1977, shall be provided with a beam monitor system ~~as follows~~ that:

~~a. It shall include a transmission detector which is a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter.~~

a. shall have the detector of the monitor system interlocked to prevent incorrect positioning;

~~b. It shall have the detector interlocked to prevent incorrect positioning in the useful beam.~~

b. shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;

~~c. It shall have a display at the control panel from whose reading in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.~~

c. shall independently terminate irradiation when the preselected exposure has been reached;

~~d. The control panel display shall maintain the reading until intentionally reset to zero.~~

d. shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

~~e. In the event of electrical power failure the reading at the control panel display may be recovered at a later time.~~

e. shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

~~f. It shall not allow irradiation until a selection of a number of dose monitor units has been made at the treatment control panel.~~

f. shall have a control panel display that maintains the administered dose reading until intentionally reset to zero; and

~~g. It shall be capable of independently terminating irradiation when a pre-selected number of dose monitor units has been reached.~~

g. shall have a control panel display that does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

9. Timer. Requirements for timers are as follows:

a. ~~A~~a timer that has a display shall be provided ~~which has a display~~ at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator~~.~~;

b. the timer shall be a cumulative timer ~~which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated.~~ that activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;

c. ~~T~~the timer shall ~~not permit an exposure if set at zero or ''off.''~~ terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

d. ~~To guard against failure of the dose monitoring systems, if present, the timer shall terminate irradiation when a pre-selected time has elapsed.~~ the timer shall permit accurate presetting and determination of exposure times as short as one second;

e. the timer shall not permit an exposure if set at zero; and

f. the timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

10. Control Panel Functions. The control panel, in addition to the displays required in other provisions of LAC 33:XV.608, shall have:

a. an indication of whether electrical power is ~~present~~ available at the control panel and if activation of the x-ray tube is possible;

b. an indication of whether x-rays are being produced;

c. ~~the~~ a means for indicating ~~kV and~~ x-ray tube potential and current;

d. ~~the~~ a means for terminating an exposure at any time;

e. a locking device ~~which~~ that will prevent unauthorized use of the x-ray system; and

f. for ~~new equipment~~ x-ray systems manufactured ~~or installed~~ after April 20, 1977, a positive display of specific filter(s) in the beam.

11. ~~Control Panel with~~Multiple Tubes. When a control panel may energize more than one x-ray tube, the following requirements apply:

a. ~~I~~it shall be possible to activate only one x-ray tube ~~during any one time interval.~~ at any time;

b. ~~T~~there shall be an indication at the control panel identifying which x-ray tube is energized~~.~~; and

c. ~~T~~there shall be an indication at the ~~x-ray~~ tube ~~if that tubehead can be energized.~~ housing assembly when that tube is energized.

12. ~~Target to Patient Distance. There shall be means of determining the target to patient distance to within 1 centimeter.~~Source-to-skin Distance. There shall be means of determining the SSD to within one centimeter.

13. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five

seconds, the ~~entire useful~~ beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:

a. after the unit is at ~~the selected~~ operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

b. an indication of shutter position shall appear at the control panel.

14. Low-filtration X-ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

B. Facility Design Requirements For X-ray Systems Capable of Operating Above 50 kVp ~~In addition to shielding adequate to meet requirements of Chapter 4 of these regulations, the following treatment room design requirements are made~~:

1. ~~Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors [preferably at eye level], which will indicate when the~~

~~useful beam is ''on.''~~Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

2. ~~Provision shall be made for two-way aural communication with the patient from the control room; however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.~~ Viewing Systems. Provisions shall be made as follows:

a. windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel; and

b. when the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

3. ~~Windows, mirror systems or closed-circuit television viewing screens or equivalent system shall be provided~~

~~to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. When the primary viewing system is by electronic means [e.g., television], an alternate viewing system shall be available as a backup in case of electronic failure.~~ Additional Requirements for X-ray Systems Capable of Operation Above 150 kVp. Additional requirements are:

a. all protective barriers shall be fixed except for entrance doors or beam interceptors;

b. the control panel shall be located outside the treatment room;

c. entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

d. when any door referred to in LAC 33:XV.608.B.3.c is opened while the x-ray tube is activated, the exposure at a distance of one meter from the source shall be

reduced to less than 100 milliroentgens (25.8 μC/kg) per hour.

~~4. Facilities which contain an x-ray system which may be operated above 150 kVp shall:~~

~~a. Have all necessary shielding [except for any beam interceptor] provided by fixed barriers,~~

~~b. Have the control panel in a protected area which is outside the treatment room or which has a door electrically connected to the control panel in such fashion that x-ray production cannot occur unless the door is closed,~~

~~c. Have all entrance doors to the treatment room electrically connected to the control panel such that x-ray production cannot occur unless the door is closed,~~

~~d. Be arranged such that if the doors referred to in LAC 33:XV.608.B.4.b and c are opened while the therapy x-ray tube is activated, either:~~

~~i. The machine shall shut off within two seconds, or~~

~~ii. The radiation at a distance of 1 meter~~

~~from the target shall be reduced to 10 mR/hr or less within two seconds.~~

~~e. If the radiation output of the x-ray tube is affected by any door opening, it shall be possible to restore the machine to full operation only by:~~

~~i. Closing the door and, subsequently,~~

~~ii. Reinitiating the exposure by manual action at the control panel.~~

C. ~~Operating Procedures, Surveys, and Calibration~~ Surveys, Calibrations, Spot Checks, and Operating Procedures

1. ~~All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the division.~~Survey requirements are as follows:

a. all new facilities, and existing facilities

not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard;

b. the registrant or licensee shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant or licensee to the division within 30 calendar days of receipt of the report; and

c. the survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules.

2. ~~The radiation output of each therapeutic x-ray machine shall be calibrated by a qualified expert. The calibration shall be repeated after any change in, or replacement of, components of the x-ray generating equipment which could cause a change in x-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is directly traceable to national standards of exposure or absorbed dose, and which shall have been calibrated within the preceding year. Records of such calibrations shall be provided to and maintained by the registrant. In addition~~ Calibrations shall

be performed as follows:

a. ~~Each therapeutic x-ray machine shall have the calibrations repeated at time intervals not exceeding one year. The calibration shall include at least the following determinations:~~the calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components that could cause a change in the radiation output;

~~i. the accurate determination of the air dose rate or the dose rate in a suitable phantom, as appropriate, for a sufficient number of operating parameters for each effective energy to permit the determination of the dose received by the patient;~~

~~ii. verification that the equipment is operating in accordance with the design specifications concerning the congruence between the radiation field and light localizer [when such is used] and for beam flatness and symmetry at the specified depths;~~

~~iii. the effective energy [e.g., half-value layer when appropriate] for every combination of kVp and filter used for radiation therapy; and~~

~~iv. the uniformity of the radiation field and its dependence upon the direction of the useful beam;~~

~~v. the calibration determinations above shall be provided in sufficient detail such that the absorbed dose in rads to tissue adjacent to, as well as in the useful beam, may be calculated to within + 5 percent of the intended absorbed dose.~~

b. ~~Therapeutic x-ray systems capable of operation at greater than 150 kVp shall, in addition to the annual calibration required in LAC 33:XV.608.C.2.a, have spot checks performed which meet the following criteria:~~the calibration of the radiation output of the x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;

~~i. A spot check shall be made at least monthly or after 50 operating hours, whichever is longer, and shall include carefully selected representative or indicative measurements which will demonstrate the consistency of relevant machine operating characteristics, or lack of same.~~

~~ii. The spot check methods shall be in writing and shall have been designed by a qualified expert. Spot checks shall include verification of continued congruency between~~

~~the radiation field and the localizing device where an optical field illuminator is used.~~

~~iii. Spot checks which are erratic or inconsistent with calibration data shall be investigated promptly.~~

~~iv. For machines in which beam quality may vary significantly, spot checks shall include beam quality checks.~~

~~v. Whenever a spot check indicates a significant change [as specified in the qualified expert's spot check design] in the operating characteristics of a machine, the machine shall be recalibrated as required in LAC 33:XV.608.C.2.a.~~

~~vi. A log shall be kept of all spot check measurements.~~

c. calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years;

d. the calibrations shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of five percent;

e. the calibration of the x-ray system shall include, but not be limited to, the following determinations:

i. verification that the x-ray system is operating in compliance with the design specifications;

ii. the exposure rates as a function of field size, technique factors, filter, and treatment distance used;

iii. the degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

iv. an evaluation of the uniformity of the largest radiation field used;

f. records of calibration shall be maintained by the registrant or licensee for five years after completion of the calibration at the facility of use; and

g. a copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

3. ~~In the therapeutic application of x-ray equipment constructed with beryllium or other low-filtration windows, the registrant shall assure that the unfiltered radiation reaches only the part intended and that the useful beam port is blocked at all times except when actually being used.~~Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

a. the spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedures shall be submitted to the division prior to their implementation;

b. if a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 calendar days;

c. the spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall

be performed during the calibration specified in LAC 33:XV.608.C.2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in LAC 33:XV.608.C.2 shall be stated;

d. the cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation;

e. whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in LAC 33:XV.608.C.2;

f. records of spot-check measurements shall be maintained by the registrant or licensee for two years after completion of the spot-check measurements and any necessary corrective actions at the facility of use; and

g. where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of LAC 33:XV.608.C.2 or that has been intercompared with a system meeting those requirements within the previous year.

4. ~~Therapeutic x-ray machines shall not be left unattended unless the locking device required by LAC 33:XV.608.A.10.e is set to prevent activation of the useful beam.~~ Operating procedures shall include the following:

a. x-ray systems shall not be left unattended unless the system is secured against unauthorized use;

b. when a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

c. the tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding, and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp;

d. no individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of LAC 33:XV.410. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp; and

e. the x-ray system shall not be used in the administration of radiation therapy unless the requirements of LAC 33:XV.608.C.2 and LAC 33:XV.608.C.3.e have been met.

~~5. Except as provided in LAC 33:XV.603.G.1.g, no individual other than the patient shall be in the treatment room during exposures unless he is protected by a barrier sufficient to meet the requirements of LAC 33:XV.410, and no individual other than the patient shall be in the treatment room when the kVp exceeds 150 during exposures except in emergency situations.~~

~~6. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.~~

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:**

§609. X-Rray and Electron Therapy ~~Installations~~ Systems with

Energies of ~~(1 MeV and Above)~~

A. ~~All of~~ LAC 33:XV.Chapter 9, except LAC 33:XV.911.C and D, shall apply to medical facilities using ~~medical~~ therapy ~~equipment~~ systems with energies of 1 MeV and above.

~~A. Equipment Requirements~~

~~1. Leakage Radiation to the Patient Area~~

~~a. [Reserved]~~

~~b. For existing equipment and new equipment manufactured or installed after April 20, 1977:~~

~~i. The leakage radiation [excluding neutrons] at a distance of one meter from the source shall not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.~~

~~ii. Prior to use the registrant shall determine or obtain from the manufacturer for each machine the leakage radiation [electrons, x-rays, neutrons] existing at the points specified in LAC 33:XV.609.A.1.b.i for specified operating conditions. Records on radiation leakage shall be maintained at~~

~~the installation.~~

~~iii. For equipment from which neutron leakage may be a hazard the secretary may, by specific order, impose upon any user such additional requirements as it deems appropriate or necessary to protect health or minimize danger to life or property. When imposing such additional requirements, the secretary will give due consideration to accepted standards of safe practice.~~

~~2. [Reserved]~~

~~3. [Reserved]~~

~~4. Beam-Limiting Devices~~

~~Adjustable or interchangeable beam-limiting devices shall be provided.~~

~~a. [Reserved]~~

~~b. For existing equipment and new equipment manufactured or installed after April 20, 1977:~~

~~i. Adjustable or interchangeable~~

~~beam-limiting devices shall attenuate the radiation incident on the beam-limiting devices such that the dose equivalent in Rems at any distance from the source does not exceed two percent of the maximum dose equivalent in the useful beam measured at an equal distance from the radiation source. The beam-limiting devices referred to in this clause do not include partial transmission-blocking devices.~~

~~ii. If the beam-limiting device does not meet the specifications in LAC 33:XV.609.A.4.b.i above, the division may accept auxiliary equipment or methods for accomplishing attenuation.~~

~~c. Dose equivalent measurements may be averaged over an area up to but not exceeding 100 cm^2; at a distance of one meter from the target. In case of overlapping beam-limiting devices, the leakage through each set shall be measured independently.~~

~~5. Filters~~

~~a. [Reserved]~~

~~b. In equipment which uses a system of wedge filters, interchangeable field flattening filters or~~

~~beam-scattering filters:~~

~~i. Irradiation shall not be possible until a selection of filter has been made at the treatment control panel.~~

~~ii. An interlock system shall be provided to prevent irradiation if the filter is not in the correct position.~~

~~iii. A display shall be provided at the treatment control panel showing the filter[s] [or zero filter] in use.~~

~~6. [Reserved]~~

~~7. Beam Monitors~~

~~Existing equipment and new equipment manufactured or installed after April 20, 1977, shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system.~~

~~a. Each detector shall be capable of independently monitoring and turning "off" the useful beam.~~

~~b. Each detector shall form part of a dose~~

~~monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.~~

~~c. Each dose monitoring system shall have a legible display at the treatment control panel which shall:~~

~~i. maintain a reading until intentionally reset,~~

~~ii. in the event of power failure, have the capability of retrieving the information displayed at the time of failure, and~~

~~iii. utilize a design such that increasing dose is displayed by increasing numbers and so designed that in the event of an overdosage of radiation, the absorbed dose may be accurately determined.~~

~~8. [Reserved]~~

~~9. Selection and Display of Dose Monitor Units~~

~~a. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the~~

~~treatment control panel.~~

~~b. After useful beam termination, it shall be necessary to reset the pre-selected dose monitor units before treatment can be reinitiated.~~

~~c. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.~~

~~10. Termination of Irradiation by the Dose Monitoring System~~

~~a. Each of the monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.~~

~~b. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been reached, and each secondary system shall be used as a backup.~~

~~11. Termination Switches~~

~~It shall be possible to terminate irradiation and~~

~~equipment movements or to go from an interruption condition to termination conditions at any time from the treatment control panel.~~

~~12. Interruption Switches~~

~~It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any re-selection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.~~

~~13. Timer~~

~~a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.~~

~~b. The timer shall be a cumulative timer which switches \\'on'' and \\'off'' with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated.~~

~~c. To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a pre-selected time has elapsed.~~

~~14. Selection of Radiation Type~~

~~In equipment capable of both x-ray therapy and electron therapy:~~

~~a. Irradiation shall not be possible until a selection of radiation type [x-rays or electrons] has been made at the treatment control panel.~~

~~b. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted.~~

~~c. The radiation-type selected shall be displayed at the treatment control panel before and during irradiation.~~

~~15. Selection of Energy~~

~~In equipment capable of generating radiation beams of different energies:~~

~~a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.~~

~~b. The energy selected shall be displayed at the treatment control panel before and during irradiation.~~

~~16. Selection of Stationary-Beam Therapy or Moving-Beam Therapy~~

~~In equipment capable of both stationary-beam therapy and moving-beam therapy:~~

~~a. Irradiation shall not be possible until a selection of stationary-beam therapy or moving-beam therapy has been made at the treatment control panel.~~

~~b. Moving-beam therapy shall be so controlled that the required dose monitor units per degree of rotation is obtained.~~

~~c. The mode of operation shall be displayed at the treatment control panel.~~

~~17. [Reserved]~~

~~18. Location of Focal Spot and Beam Orientation~~

~~The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:~~

~~a. the x-ray target and the virtual source of x-rays,~~

~~b. the electron window and/or the scattering foil, and~~

~~c. all possible orientations of the useful beam.~~

~~19. System Checking Facilities~~

~~Facilities shall be provided so that all radiation safety interlocks can be checked. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.~~

~~B. Facility and Shielding Requirements~~

~~Shielding shall be adequate to meet the requirements of Chapter 4 of these regulations and, in addition, the following design requirements apply.~~

~~1. Except for entrance doors, all the required barriers shall be fixed barriers.~~

~~2. The control panel shall be located outside the treatment room or within a protective booth equipped with an interlocked door which is electrically connected to the control panel in such a fashion that the door must be closed during radiation production.~~

~~3. Windows, mirror systems, closed-circuit television viewing screens or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. When the viewing system is by electronic means [e.g., television], an alternate viewing system shall be provided for use in the event of failure of the primary system.~~

~~4. Provision shall be made for two-way aural communication with the patient from the control station. However, where excessive noise levels make aural communication~~

~~impractical, other methods of communication shall be used.~~

~~5. Treatment rooms shall be provided with warning lights in a readily observable position near the outside of all access doors which will indicate when the useful beam is ''on.''~~

~~6. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and, subsequently, reinitiating exposure by manual action at the control panel.~~

B. In addition to the definitions provided in LAC 33:XV.602, the following definitions shall be applicable to LAC 33:XV.609:

Applicator—a structure that determines the extent of the treatment field at a given distance from the virtual source.

Beam-scattering Filter—a filter used to scatter a beam of electrons.

Central Axis of the Beam—a line passing through the virtual source and the center of the plane figure formed by the

edge of the first beam-limiting device.

Dose-monitoring System—a system of devices for the detection, measurement, and display of quantities of radiation.

Dose Monitor Unit—a unit response from the dose-monitoring system from which the absorbed dose can be calculated.

Existing Equipment—therapy systems subject to LAC 33:XV.609 that were manufactured on or before January 1, 1985.

Field-flattening Filter—a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

Field Size—the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line.

Gantry—that part of the system supporting and allowing possible movements of the radiation head.

Interruption of Irradiation—the stopping of irradiation

with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Isocenter—a fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions. The sphere is described by the intersection of the axes of rotation of the gantry, the collimator, and the couch.

Moving Beam Therapy—radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

New Equipment—systems subject to LAC 33:XV.609 that were manufactured after January 1, 1985.

Nominal Treatment Distance—

a. for electron irradiation, the nominal source-to-surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

b. for x-ray irradiation, the nominal source-to-isocenter distance along the central axis of the useful beam.

For non-isocentric equipment, this distance shall be that specified by the manufacturer.

Radiation Head—the structure from which the useful beam emerges.

Shadow Tray—a device attached to the radiation head to support auxiliary beam limiting material.

Stationary Beam Therapy—radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Target—that part of a radiation head that by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Virtual Source—a point from which radiation appears to originate.

C. ~~Operating Procedures~~ Requirements for Equipment

1. ~~Radiation Protection Survey~~ Leakage Radiation to the Patient Area. Requirements are as follows:

a. ~~All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by a radiological physicist. This shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.~~ new equipment and existing equipment manufactured or installed after April 20, 1977, shall meet the following requirements:

i. for operating conditions producing maximum leakage radiation, the absorbed dose in rads (centigrays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (centigrays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters; and

ii. for each system, the registrant or

licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in LAC 33:XV.609.C.1.a.i for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the division; and

b. ~~The expert shall report his findings in writing to the person in charge of the facility, and a copy of the report shall be transmitted by the registrant to the division.~~ existing equipment shall meet the following requirements:

i. for operating conditions producing maximum leakage radiation, the absorbed dose in rads (centigrays) due to leakage radiation excluding neutrons at any point in a circular plane of two meters radius centered on a perpendicular to the central axis of the beam one meter from the nominal source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (centigrays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified; and

ii. for each system, the registrant or licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in LAC 33:XV.609.C.1.b.i for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the division.

~~c. The survey and report shall indicate all instances where, in the opinion of the radiological physicist, the installation is in violation of applicable therapy radiation protection regulations and shall cite the sections violated.~~

2. ~~Holding Patients. No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.~~ Leakage Radiation Outside the Patient Area for New Equipment. Requirements are as follows:

a. the absorbed dose in rads (centigrays) due to leakage radiation except in the area specified in LAC 33:XV.609.C.1.a.i when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose

in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plan specified in LAC 33:XV.609.C.1.a.i; and

b. the registrant or licensee shall determine or obtain from the manufacturer the actual leakage radiation existing at the positions specified in LAC 33:XV.609.C.2.a for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

3. ~~Calibrations~~

~~The output of each therapeutic x-ray machine shall be calibrated by a radiological physicist, before it is first used for medical purposes. Calibrations shall be repeated at least once every 12 months and after any change which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is directly traceable to national standards of exposure or absorbed dose and which shall have been calibrated within the preceding year. Records of calibrations shall be provided to and maintained by the registrant. The calibration shall include at least the following determinations:~~

Reserved

~~a. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and backpointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depths.~~

~~b. The exposure rate or dose rate for the range and field sizes used and for each effective energy and for each treatment distance used for radiation therapy.~~

~~c. The effective energy [e.g., half-value layer when appropriate] for every combination of kVp and filter used for radiation therapy.~~

~~d. The congruence between the radiation field and the field indicated by the localizing device when localizing devices are used for radiation therapy.~~

~~e. The uniformity of the radiation field and its dependence upon the direction of the useful beam.~~

~~f. The calibration determinations above shall be~~

~~provided in sufficient detail such that the absorbed dose in rads to tissue adjacent to, as well as in the useful beam, may be calculated to within + 5 percent of the intended absorbed dose.~~

4. ~~Spot checks~~ Beam-limiting Devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam that is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

~~a. A spot check shall be made daily with use and shall include carefully selected representative or indicative measurements which will demonstrate the consistency of relevant machine operating characteristics or lack of same.~~

~~b. The spot check methods shall be in writing and shall have been designed by a radiological physicist.~~

~~c. Spot checks which are erratic or inconsistent with calibration data shall be investigated promptly.~~

~~d. For machines in which beam quality may vary significantly, spot checks shall include beam quality checks.~~

~~e. Whenever a spot check indicates a significant change [as specified in the radiological physicist's spot check design] in the operating characteristics of a machine, the machine shall be recalibrated as required in LAC 33:XV.609.C.3.~~

~~f. Where a machine has built-in devices which provide a self-check of any parameter during irradiation, that parameter may be spot checked weekly instead of daily.~~

~~g. A log shall be kept of all spot check measurements.~~

5. Filters. Filters shall meet the following requirements:

a. each filter that is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray;

b. if the absorbed dose rate data required by LAC 33:XV.609.C.16 relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall be removable only by the use of tools; and

c. for new equipment that utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering filters:

i. irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

ii. an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

iii. a display shall be provided at the treatment control panel showing the filter(s) in use; and

iv. an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

6. Beam Quality. The registrant or licensee shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

a. the absorbed dose resulting from x-rays in a

useful electron beam at the point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table 2. Linear interpolation shall be used for values not stated:

Table 2

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

b. compliance with LAC 33:XV.609.C.6.a shall be determined using:

i. a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

ii. the largest field size available that does not exceed 15 by 15 centimeters; and

iii. a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement;

c. the absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table 3. Linear interpolation shall be used for values not stated:

Table 3

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

d. compliance with LAC 33:XV.609.C.6.c shall be determined by measurements made:

i. within a phantom using an instrument that will allow extrapolation to the surface absorbed dose;

ii. using a phantom whose size and placement meet the requirements of LAC 33:XV.609.C.6.b;

iii. after removal of all beam modifying devices that can be removed without the use of tools, except for beam-scattering or field-flattening filters; and

iv. using the largest field size available that does not exceed 15 by 15 centimeters; and

e. the registrant or licensee shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

7. Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head. The following requirements apply:

a. new equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose-monitoring systems;

b. existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose-monitoring system; and

c. the detector and the system into which that detector is incorporated shall meet the following requirements:

i. each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning;

ii. each detector shall form part of a dose-monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;

iii. each dose-monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

iv. for new equipment, the design of the

dose-monitoring systems shall assure that:

(a). the malfunctioning of one system shall not affect the correct functioning of the second system; and

(b). the failure of any element common to both systems that could affect the correct function of both systems shall terminate irradiation; and

v. each dose-monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

(a). maintain a reading until intentionally reset to zero;

(b). have only one scale and no scale multiplying factors;

(c). utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

(d). in the event of power failure, the dose-monitoring information required by LAC 33:XV.609.C.7.c.v displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

8. Beam Symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of this condition is made at the control panel, and if this difference exceeds 10 percent, the irradiation is terminated.

9. Selection and Display of Dose Monitor Units. The following requirements shall be met:

a. irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;

b. after termination of irradiation, it shall be

necessary to reset the dosimeter display to zero before subsequent treatment can be initiated;

c. the preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation; and

d. for new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

10. Termination of Irradiation by the Dose-monitoring System or Systems During Stationary Beam Therapy. The following requirements shall be met:

a. if the original design of the equipment included a second dose-monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel have been detected by the second dose-monitoring system;

b. each primary system shall terminate irradiation when the preselected number of dose monitor units has

been detected by the system;

c. for new equipment, a second dose-monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitor units above the preselected number of dose monitor units set at the control panel have been detected by the second dose-monitoring system; and

d. for new equipment, an indicator on the control panel shall show which dose-monitoring system has terminated irradiation.

11. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

12. Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time

from the operator's position at the treatment control panel.

13. Timer. Requirements for timers are as follows:

a. a timer that has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

b. the timer shall be a cumulative timer that activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;

c. the timer shall terminate irradiation when a preselected time has elapsed if the dose-monitoring systems have not previously terminated irradiation; and

d. for new equipment, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

14. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following

additional requirements:

a. irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel;

b. the radiation type selected shall be displayed at the treatment control panel before and during irradiation;

c. an interlock system shall be provided to ensure that the equipment can emit only the radiation type selected;

d. an interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

e. an interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted; and

f. an interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

15. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

a. irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

b. the nominal energy value selected shall be displayed at the treatment control panel before and during irradiation;

c. an interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and

d. for new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

16. Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

a. irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;

b. an interlock system shall be provided to ensure that the equipment can operate only in the mode selected;

c. the mode of operation shall be displayed at the treatment control panel;

d. an interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

e. for new equipment, an interlock system shall be provided to terminate irradiation if:

i. movement of the gantry occurs during stationary beam therapy; or

ii. movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function;

f. moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

i. for new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value; and

ii. for new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle relationship; and

g. where the dose-monitoring system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by LAC 33:XV.609.C.9.

17. Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified may form part of this system. In addition:

a. the dose monitor unit rate shall be displayed

at the treatment control panel; and

b. if the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided that terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant or licensee.

18. Location of Virtual Source and Beam Orientation. The registrant or licensee shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

a. the x-ray target or the virtual source of x-rays; and

b. the electron window or the virtual source of electrons if the system has electron beam capabilities.

19. System-checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating

conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

D. Facility and Shielding Requirements. In addition to LAC 33:XV.Chapter 4, the following design requirements shall apply:

1. Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

2. Control Panel. The control panel shall be located outside the treatment room.

3. Viewing Systems. Provisions shall be made as follows:

a. windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel; and

b. when the primary viewing system is by electronic means, an alternate viewing system, which may be

electronic, shall be available for use in the event of failure of the primary viewing system.

4. Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

5. Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".

6. Entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

E. Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Survey requirements are as follows:

a. all new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard;

b. the registrant or licensee shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant or licensee to the division within 30 days of receipt of the report; and

c. the survey and report shall indicate all instances in which the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

2. Calibrations shall be performed as follows:

a. the calibration of systems subject to LAC 33:XV.609 shall be performed in accordance with an established calibration protocol acceptable to the division before the system is first used for irradiation of a patient and thereafter at intervals that do not exceed 12 months, and after any change that might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The calibration

protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the division for written concurrence that the protocol is acceptable;

b. the calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration;

c. calibration radiation measurements required by LAC 33:XV.609.E.2.a shall be performed using a dosimetry system:

i. that has a calibration factor for cobalt-60 gamma rays traceable to a national standard;

ii. that has been calibrated within the previous two years and after any servicing that may have affected its calibration;

iii. that has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

iv. that has had constancy checks performed on the system as specified by a radiological physicist;

d. calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent;

e. the calibration of the therapy beam shall include but not be limited to the following determinations:

i. verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable; variation in the axis of rotation for the table, gantry, and jaw system; and beam flatness and symmetry at the specified depth;

ii. the absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures used with that therapy beam;

iii. the uniformity of the radiation field and any dependency upon the direction of the useful beam;

iv. verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine

conditions; and

v. verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators;

f. records of calibration measurements under LAC 33:XV.609.E.2.a and dosimetry system calibrations under LAC 33:XV.609.E.2.c shall be maintained for five years after completion of the full calibration at the facility of use; and

g. a copy of the latest calibration performed pursuant to LAC 33:XV.609.E.2.a shall be available in the area of the control panel.

3. Spot checks shall be performed on systems subject to LAC 33:XV.609 during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

a. the spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the division prior to its implementation;

b. if a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days;

c. the spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check compared to the value for that parameter determined in the calibration;

d. at intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of one depth in a phantom;

e. where a system has built-in devices that provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement;

f. the cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation;

g. wherever a spot check indicates a significant change in the operating characteristics of a system, as specified

in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in LAC 33:XV.609.E.2;

h. records of spot-check measurements shall be maintained by the registrant or licensee for a period of two years after completion of the spot-check measurements and any necessary corrective actions at the facility of use; and

i. where a spot check involves a radiation measurement, such measurement shall be obtained using a system that satisfies the requirements of LAC 33:XV.609.E.2.c or that has been intercompared with a system meeting those requirements within the previous year.

4. Operating procedures shall include the following:

a. no individual other than the patient shall be in the treatment room during treatment of a patient;

b. if a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

c. the system shall not be used in the administration of radiation therapy unless the requirements of

LAC 33:XV.609.E.1, 2, and 3 have been met.

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:**

§610. ~~Veterinary Medicine Radiographic Installations~~ Computed Tomography X-ray Systems

A. ~~Equipment~~ In addition to the definitions provided in LAC 33:XV.102 and LAC 33:XV.602, the following definitions shall be applicable to this Section:

Contrast Scale—the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

μ_x = linear attenuation coefficient of the material of interest;

μ_w = linear attenuation coefficient of water;

$(CTN)_x$ = CTN of the material of interest; and

$(CTN)_w$ = CTN of water.

CS—(See *Contrast Scale.*)

CT Conditions of Operation—all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in LAC 33:XV.602.

CT Gantry—the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

CTN—(See *CT Number.*)

CT Number—the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

Dose Profile—the dose as a function of position along a line.

Elemental Area—the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also *Picture Element*.)

Multiple Tomogram System—a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of

water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = contrast scale;

μ_w = linear attenuation coefficient of water; and

s = estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

Nominal Tomographic Section Thickness—the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

Picture Element—an elemental area of a tomogram.

Reference Plane—a plane that is displaced from and parallel to the tomographic plane.

Scan—the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be

collected simultaneously during a single scan for the production of one or more tomograms.

Scan Increment—the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

Scan Sequence—a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan Time—the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Single Tomogram System—a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

Tomographic Plane—that geometric plane identified as corresponding to the output tomogram.

Tomographic Section—the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

~~1. The protective tube housing shall be of the diagnostic type.~~

~~2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.~~

~~3. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.~~

~~4. A device shall be provided to terminate the exposure after a preset time or exposure.~~

~~5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures.~~

B. ~~Structural Shielding~~

~~All wall, ceiling and floor areas shall be equivalent~~

~~to or provided with applicable protective barriers as required in LAC 33:XV.603.J.1 and 2.~~ Requirements for Equipment

1. Termination of Exposure. Requirements are as follows:

a. a means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices that monitor equipment function;

b. a visible signal shall indicate when the x-ray exposure has been terminated through the means required by LAC 33:XV.610.B.1.a; and

c. the operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than 0.5 second duration.

2. Tomographic Plane Indication and Alignment. Requirements are as follows:

a. for any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane;

b. for any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes; and

c. if a device using a light source is used to satisfy LAC 33:XV.610.B.2.a or b, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam On and Shutter Status Indicators and Control Switches. The following requirements shall be met:

a. the CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed; and

b. each emergency button or switch shall be clearly labeled as to its function.

4. Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

5. Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by LAC 33:XV.604.A.3.

6. Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985, are as follows:

a. the total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters;

b. if the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be discernible from any point external to the patient opening

where insertion of any part of the human body into the primary beam is possible;

c. the deviation of indicated scan increment versus actual increment shall not exceed ±1 millimeter with any mass from zero to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel; and

d. premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

C. ~~Operating Procedures~~ Facility Design Requirements

1. ~~The operator shall stand well away from the useful beam and the animal during radiographic exposures.~~ Aural Communication. Provision shall be made for two way aural communication between the patient and the operator at the control panel.

2. ~~No individual other than the operator shall be in~~

~~the x-ray room while exposures are being made unless such individual's assistance is required.~~ Viewing Systems. Provisions shall be made as follows:

a. windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel; and

b. when the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

~~3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual routinely used for this purpose shall be monitored and permanently recorded.~~

D. Surveys, Calibrations, Spot Checks, and Operating

Procedures

1. Survey requirements are as follows:

a. all CT x-ray systems installed after February 20, 1991, and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard; and

b. the registrant or licensee shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the division upon request.

2. Radiation calibrations shall be performed as follows:

a. the calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;

b. the calibration of a CT x-ray system shall be

performed at intervals specified by a qualified expert and after any change or replacement of components that, in the opinion of the qualified expert, could cause a change in the radiation output;

c. the calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years at the facility of use;

d. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

i. CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 ±0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

ii. CT dosimetry phantom(s) shall provide a means for the placement of a dosimeter or dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. A means for the placement of dosimeters or alignment devices at other locations may be provided;

iii. any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

iv. all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present;

e. the calibration shall be required for each type of head, body, or whole-body scan performed at the facility of use;

f. calibration shall meet the following requirements:

i. the dose profile along the center axis of

the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant or licensee shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; and

ii. the spot checks specified in LAC 33:XV.610.E.3 shall be made; and

g. calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the division.

3. Spot checks shall meet the following requirements:

a. the spot-check procedures shall be in writing and shall have been developed by a qualified expert;

b. the spot-check procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, and the resolution capability of the system for low and high contrast objects, and for measuring the mean CTN for water or other reference material;

c. all spot checks shall be included in the calibration required by LAC 33:XV.610.E.2 and at time intervals and under system conditions specified by a qualified expert;

d. spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by LAC 33:XV.610.E.2. The images shall be retained, until a new calibration is performed, in either of two forms as follows:

i. photographic copies of the images obtained from the image display device; or

ii. images stored in digital form on a storage medium compatible with the CT x-ray system; and

e. written records of the spot checks performed shall be maintained for inspection by the division.

4. Operating procedures shall include the following:

a. the CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation;

b. information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

i. dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

ii. instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

iii. the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

iv. a current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination; and

c. if the calibration or spot check of the CT x-ray system identifies that a system operating parameter has

exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

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:**

~~§611. Podiatric Radiographic Installations~~

~~A. Equipment~~

~~1. The protective tube housing shall be of the diagnostic type.~~

~~2. For systems utilizing rectangular x-ray fields, any dimension of the x-ray field shall not exceed the corresponding dimension of the image receptor by more than three percent of the SID.~~

~~3. For systems utilizing circular x-ray fields, the diameter of the x-ray field shall not exceed the diagonal dimension of the image receptor.~~

~~4. Except as specified in LAC 33:XV.611.A.5 below, techniques that require the plane of the image receptor to be oblique to the x-ray beam axis are exempt from the requirements of LAC 33:XV.611.A.2 or 3 if these requirements are met when the plane of the image receptor is perpendicular to the beam axis.~~

~~5. For equipment installed, purchased or transferred after April 20, 1977, the requirements of LAC 33:XV.606.A shall apply and the requirements or provisions of LAC 33:XV.611.A.4 are not applicable.~~

~~6. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.~~

~~7. A device shall be provided to terminate the exposure after a preset time or exposure.~~

~~8. Each x-ray control shall be designed in such a way as to meet the following criteria:~~

~~a. The exposure switch shall be operated in a protected area and the operator shall remain in that protected area during the entire exposure.~~

~~b. The operator's protected area shall provide visual indication of the patient during the x-ray procedure.~~

~~c. The x-ray control shall provide visual or audible indication whenever x-rays are produced.~~

~~9. Timer Reproducibility.~~

~~When four timer tests are performed at identical timer settings equal to 0.5 seconds or less, the average time period T shall be greater than five times the difference between the maximum period T_{max} and the minimum period T_{min} in accordance with the formula:~~

$$\bar{T} > 5 [T_{max} - T_{min}]$$

~~10. Exposure Reproducibility.~~

~~The exposure produced shall be reproducible to within the following criteria:~~

~~When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to have been met if, when four exposures at identical technique factors are made, the value of the average exposure E is greater than five times the difference between the maximum exposure E_{max} and the minimum exposure E_{min} in accordance with the formula:~~

$$\bar{E} > 5 [E_{max} - E_{min}]$$

~~B. Structural Shielding~~

~~All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers as defined in LAC 33:XV.602.A [See *Protective Barrier*].~~

~~C. Operating Procedures~~

~~The registrant shall comply with applicable provisions of Sections 603 and 604.~~

~~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)~~

CHAPTER 6

Appendices

Chapter 6

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the ~~D~~division to provide an evaluation ~~and/or~~, technical advice, and ~~to request~~ official approval ~~on~~of shielding requirements for a radiation installation, the following information ~~is needed.~~ shall be submitted:

A. The plans should show, as a minimum, the following:

1. The normal location of the x-ray system's radiation producing equipment's radiation port~~;~~, the port's travel and traverse limits~~;~~, general direction(s) of the ~~radiation~~ useful beam~~;~~, locations of any windows~~;~~ and doors, the location of the operator's booth~~;~~, and the location of the ~~equipment's~~ x-ray control ~~console~~ panel.

2. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

3. ~~Height, floor to floor, of the room[s] concerned~~

The dimensions of the room(s) concerned.

4. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest ~~existing occuied~~ area(s) where it is likely that individuals may be present.

5. The make and model of the ~~radiation-producing~~ x-ray equipment ~~including the maximum energy output (for x-ray machines, this is the kilovolt peal potential)~~ and the maximum technique factors.

6. The type of examination(s) or treatment(s) ~~which~~ that will be performed with the equipment ~~(e.g., dental, orthodontal, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc.)~~.

B. Information on the anticipated workload ~~used in shielding calculations shall be provided to the Division~~ of the x-ray system(s) shall be submitted with the plans.

C. If the services of a qualified ~~radiation~~ expert have been utilized~~, a copy of his report shall be submitted with the plans. This report must show all basic assumptions [i.e.,~~

~~workload, occupancy and use factors, distance, etc.] used to determine the shielding requirements~~ to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

Chapter 6

APPENDIX B

~~Minimum Design Requirements for an X-ray Machine Operator's Booth~~

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

A. Space Requirements. The operator shall be allotted not less than ~~0.8 square meter~~ 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth. ~~The booth must protect the operator from the useful beam and any radiation which has been scattered only once.~~

1. ~~The minimum space as indicated above~~ The operator's booth may be any geometric configuration ~~but~~ with no dimension of less than ~~60 centimeters~~ two feet (0.61 m).

2. The space shall be allotted excluding any encumbrance by the ~~console~~ x-ray control panel, such as overhang, cables, or other similar encroachments.

~~3. An extension of a straight line drawn between any point on the edge of the booth shielding and~~

~~a. a point 30 centimeters horizontally beyond the~~

~~nearest vertical edge of the chest cassette holder; or~~

~~b. any corner of the examination table shall not impinge on the unobstructed space.~~

3. The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette does not reach the operator's station in the booth.

~~4. The booth walls shall be at least 2.1 meters high and shall be permanently fixed to the floor or other structure as may be necessary.~~

~~5. When a door or movable panel is used as an integral part of the booth structure, it must have a permissive device which will prevent an exposure when the door or panel is not closed [this type of booth structure is not recommended].~~

B. ~~Switch Placement.~~ Structural Requirements. ~~The operator's switch for the radiographic machine shall be fixed within the booth and:~~ The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.

1. ~~Shall be at least 1 meter from any open edge of the~~

~~booth wall which is proximal to the examining table~~ When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed.

2. ~~Shall allow the operator to use the majority of the available viewing window[s]~~ Shielding shall be provided to meet the requirements of LAC 33:XV.Chapter 4.

C. ~~Viewing System Requirements.~~ X-Ray Control Placement. The x-ray control for the system shall be fixed within the booth and:

1. ~~Each booth shall have at least one viewing device which will:~~ shall be at least 40 inches (1.02 m) from any open edge of the booth wall that is nearest to the examining table; and

~~a. Be so placed that the operator can view the patient during any exposure, and~~

~~b. Be so placed that he can have full view of any occupant of the room and should be so placed that he can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have a~~

~~permissive device controlling the exposure which will prevent the exposure if the door is not closed.~~

~~2. When the viewing system is a window, the following requirements also apply:~~

2. shall allow the operator to use the majority of the available viewing windows.

~~a. It shall have a visible area of at least 925 square centimeters, the base of which is at least 135 centimeters above the floor.~~

~~b. The distance between the proximal edge of the window and the open edge of the booth shall not be less than 45 centimeters.~~

~~c. The glass shall have at least the same lead equivalence as that required in the booth's wall in which it is to be mounted.~~

~~3. When the viewing system is by mirrors: The mirror[s] shall be so located as to accomplish the general requirements as in Paragraph 1 above.~~

~~4. When the viewing system is by electronic means [e.g., TV etc.]:~~

~~a. the camera shall be so located as to accomplish the general requirements in Paragraph 1 above, and~~

~~b. there shall be an alternate viewing system as a back up in case of electronic failure.~~

D. Viewing System Requirements

1. Each booth shall have at least one viewing device that will be so placed that:

a. the operator can view the patient during any exposure; and

b. the operator can have full view of any occupant of the room, and the operator can view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure that will prevent the exposure if the door is not closed.

2. When the viewing system is a window, the following

requirements also apply:

a. the viewing area shall be at least one square foot (0.0929 m^2);

b. the design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 meter) from the edge of the booth; and

c. the material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

3. When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements in Subsection C.1 of this Appendix.

4. When the viewing system is by electronic means:

a. the camera shall be so located as to accomplish the general requirements of Subsection C.1 of this Appendix; and

b. there shall be an alternate viewing system as

a backup for the primary system.

Chapter 6

APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS

PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting ~~approval of a healing arts screening program~~ that the division approve a healing arts screening program shall submit the following information ~~for~~ and evaluation:

A. Name and address of the applicant and, where applicable, the names and addresses of agents within ~~this state~~ Louisiana.

B. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

C. A detailed description of the x-ray examinations proposed in the screening program.

D. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

E. An evaluation of any ~~other~~ known alternate methods not involving ionizing radiation ~~which~~ that could achieve the goals of the screening program and why these methods are not used ~~in perference~~ instead ~~to~~ of the x-ray examinations.

F. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of ~~these regulations~~ LAC 33:XV.

G. A description of the diagnostic film quality control program.

H. A copy of the technique chart for the x-ray examination procedures to be used.

I. The qualifications of each individual who will be operating the x-ray system(s) ~~in this state~~.

J. The qualifications of ~~the~~ each individual who will be supervising the operator(s) of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

K. The name and address of the ~~properly licensed~~

~~practitioner of the healing arts~~ individual who will interpret the radiograph(s).

L. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts, the results of ~~that~~ the screening procedure and any further medical needs indicated.

M. A description of the procedures for the retention or disposition of the radiograph(s) and other records pertaining to the x-ray examination(s).

N. The name and address of the responsible party and service agent in the event legal charges or allegations arise as a result of the x-ray screening.

O. In the event the applicant is a foreign corporation, documents shall be submitted to demonstrate that the applicant has complied with ~~this state's~~ Louisiana laws regarding domestication of that corporation.

P. Any other information requested by the division ~~which~~ that may be necessary to evaluate the justification or possible effects of an x-ray screening proposal.

~~APPENDIX D~~

~~X-Ray Film Developing Guidelines~~

~~A. Processing of Film.~~

~~All films should be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if either of the following items can be met:~~

~~1. film manufacturers published recommendations with regard to time and temperature are followed, or~~

~~2. each film manually processed is developed in accord with the following time-temperature chart:~~

~~Thermometer Readings/Degrees C F~~		~~Minimum Developing Times/Minutes~~
~~27 —~~	~~80~~	~~2~~
	~~79~~	~~2~~
	~~78~~	~~2½~~
	~~77~~	~~2½~~

Thermometer Readings/Degrees C	F	Minimum Developing Times/Minutes
24	76	3
	75	3
	74	3½
	73	3½
22	72	4
	71	4
	70	4½
	69	4½
20	68	5
	67	5½
	66	5½
	65	6
18	64	6½
	62	8
	61	8½
16	60	9½

B. Manual Processing of Film.

1. Where film is developed manually, a system should

~~be available which consists of at least one three-section tank made of mechnically rigid, corrosion resistant material [each section of which should be constructed so as to retain its solution separation from the other two] and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 16°C to 27°C [60p80°F].~~

~~2. Devices should be available which will:~~

~~a. give the actual temperature of the developer,~~ and

~~b. give an audible or visible signal, after a preset time [in minutes of duration].~~

~~3. Chemical-Film Processing Control.~~

~~a. Chemicals should be mixed in accord with the chemical manufacturer's recommendations.~~

~~b. Developer replenisher should be periodically added to the developer tank based on the area of the films which have been developed [e.g., 1 liter per 3100 in^2 of film or in accord with the recommendations of the chemical manufacturer].~~

~~Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.~~

~~c. All processing chemicals should be completely replaced at least every three months.~~

~~d. At the time of the complete processing chemical change, a film should be exposed to a density of approximately one, with one-half of the film being protected from the exposure. After full development, it will be maintained in the darkroom or vicinity and, at the beginning of each work day, at least one test film or film strip [exposed under techniques identical with those used for the original test film] should be compared with the original test film to evaluate the adequacy of developing results and base fog level.~~

~~C. Automatic Processors and Other Closed Processing Systems.~~

~~1. Preventive maintenance should be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule should be established which will preserve good film quality.~~

~~2. After a full cleansing of the processor, a film should be exposed to a density of approximately one, with one-half of the film protected from exposure. It will be developed and then kept near the unit and daily at least one test film [exposed under techniques identical with those used for the original test film] should be compared with the original test film to evaluate the adequacy of the unit's developing capability and base fog level.~~

~~D. Darkrooms.~~

~~1. Darkrooms should be constructed so that film being processed, handled or stored will be exposed only to light which has passed through a safelight filter.~~

~~2. The radiance and spectral emission of the safelight, when used, [bulf and filter combination] should be such that film shall not be ''fogged'' above the base level when exposed for 1 minute at a distance of about 1.2 meters from the lamp[s]. Film manufacturer's recommendations for a safelight and its placement shall be adjudged to meet this criterion.~~

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 9. Radiation Safety Requirements for Particle Accelerators

§901. Purpose and Scope

A. This Chapter establishes procedures for the registration and licensing, and for the use of particle accelerators.

B. In addition to the requirements of this Chapter, all registrants and/or licensees are subject to the applicable requirements of LAC 33:XV.Chapters 1 and 2 and/or LAC 33:XV. Chapters 3, 4, and 10. Registrants and licensees engaged in industrial radiographic operations are subject to the requirements of LAC 33:XV.Chapter 5, and registrants and/or licensees engaged in the healing arts are subject to the requirements of LAC 33:XV.Chapter 6 and/or LAC 33:XV.Chapter 7 ~~of these regulations~~. All licensees and registrants ~~that are engaged~~whose operations result in the production of radioactive material are subject to the requirements of 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, Nuclear Energy Division, LR 13:569 (October 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:**

Subchapter A. Registration and Licensing Procedures

§902. Registration and License Requirements

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration and/or license issued pursuant to ~~these regulations~~LAC 33:XV or as otherwise provided for in ~~these regulations~~LAC 33:XV. The general procedures for registration of particle accelerator facilities are included in LAC 33:XV.Chapter 2 ~~of these regulations~~, while the general procedures for licensing are included 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, Nuclear Energy Division, LR 13:569

(October 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:**

§903. General Requirements for the Issuance of a Registration or License for Particle Accelerators

In addition to the requirements of LAC 33:XV.Chapters 2 and 3, a registration and/or license application for use of a particle accelerator will be approved only if the division determines that:

~~A~~1. the applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Chapter and LAC 33:XV.Chapters 4 and 10 ~~of these regulations~~ in such a manner as to minimize danger to public welfare and safety or property;

~~B~~2. the applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public welfare and safety or property;

~~C~~3. the issuance of the registration and/or license will not be inimical to the welfare and safety of the public, and

the applicant satisfies any applicable special requirement in ~~Section 904 of this regulation~~LAC 33:XV.904;

~~D~~4. the applicant has appointed a radiation safety officer;

~~E~~5. the applicant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application in ~~its~~their intended uses;

~~F~~6. the applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators; and

~~G~~7. the applicant has an adequate training program for particle accelerator operators.

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:**

§904. Human Use of Particle Accelerators

In addition to the requirements set forth in LAC 33:XV. Chapters 2 and 3, a registration and/or license for use of a particle accelerator in the healing arts will be issued only if the following criteria are met:

~~A~~1. ~~T~~the applicant has appointed a medical committee of at least three members to evaluate all proposals for research. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and/or a person experienced in depth dose calculations and protection against radiation. The committee is not required if research will not be performed with the accelerator~~.~~;

~~B~~2. ~~T~~the individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans~~.~~; and

~~C~~3. ~~E~~each individual designated on the application as a user is a physician.

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:**

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

~~§905. General Provisions~~

~~A. This Section establishes radiation safety requirements for the use of particle accelerators. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of the Louisiana Radiation Regulations.~~

~~B. The registrant and/or licensee shall be responsible for assuring that all requirements of this Chapter are met.~~

~~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)~~

§905. Reserved

§906. Limitations

A. No registrant and/or licensee shall permit any person to act as a particle accelerator operator until such person:

1. has been instructed in radiation safety and shall have demonstrated an understanding thereof;

2. has received copies of and instruction in this Chapter and the applicable requirements of LAC 33:XV.Chapters 4 and ~~Chapter~~ 10, pertinent registration and/or license conditions, and the registrant's and/or licensee's operating and emergency procedures, and shall have demonstrated understanding thereof; and

3. has demonstrated competence to use the particle accelerator, related equipment, and survey instruments ~~which~~that will be employed in his or her assignment.

B. Either the radiation safety committee or the radiation safety officer, in addition to duly authorized representatives of the division, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to ~~protect health and~~ minimize danger to public welfare and safety or property.

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:**

§907. Shielding and Safety Design Requirements

A. A qualified expert, specifically accepted in writing by the division, shall be consulted in the design of a particle accelerator installation and shall be called upon to perform a radiation survey when the accelerator is first capable of producing radiation. A copy of the survey shall be submitted to the division.

B. Plans for construction of new accelerator installations shall be submitted to the division for approval prior to ~~completion~~commencement of construction.

C. Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with LAC 33:XV.410 and ~~41~~422.

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:**

§908. Particle Accelerator Controls and Interlock Systems

A. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, legible, and easily discernible.

B. All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration or intrusion.

C. When an interlock system has been tripped, it shall be possible to resume operation of the accelerator only by manually resetting controls at the position where the interlock has been tripped and, lastly, at the main control console.

D. Each radiation safety interlock shall be on a circuit ~~which~~that shall allow its operation independently of all other safety interlocks.

E. All radiation safety interlocks shall be fail-safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

F. A "scram button" or other emergency power cut-off switch shall be located and easily identifiable in all high radiation areas. Such a cut-off switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the emergency power cut-off switch.

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:**

§909. Warning Devices

A. All locations designated as high radiation areas, and entrances to such locations, shall be equipped with easily observable ~~flashing or rotating~~ warning lights that operate when, and only when, radiation is being produced.

B. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device ~~which~~that shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible and audible in all high radiation areas ~~and all radiation areas~~.

C. Except in facilities designed for human exposure, ~~B~~barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified by posting signs in accordance with ~~Section~~ LAC 33:XV.4~~22~~50.

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:**

§910. Operating Procedures

A. Particle accelerators, when not in operation, shall be secured in a manner ~~which~~that will prevent unauthorized use.

* * *

F. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel at all times.

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:**

§911. Radiation Monitoring Requirements

A. There shall be available at each particle accelerator facility appropriate portable monitoring equipment ~~which~~that is operable and ~~which~~that has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and also after servicing and repair.

B. A radiation protection survey shall be performed, documented, and submitted to the division by a qualified expert specifically approved in writing by the ~~D~~division when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

C. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and shall be capable of providing a ~~remote and local~~ readout ~~with visual and/or audible alarms~~ at ~~both~~ the control panel ~~and at entrances to high radiation areas and other appropriate locations so that people entering or present become aware of the existence of the hazard~~.

D. All area monitors shall be calibrated at intervals not to exceed one year and <u>also</u> after each servicing and repair.

* * *

H. Records of all radiation protection surveys, calibrations~~ results~~, <u>and</u> instrumentation tests ~~and smear results~~ shall be ~~kept current and on file for inspection by the division at each accelerator facility for a period of two years~~<u>maintained at each accelerator facility for inspection by the division</u>.

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:**

§912. Ventilation Systems

A. A Mmeans shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in LAC 33:XV.Chapter 4, Appendix A, Table I ~~of these regulations~~.

B. A registrant and/or licensee, as required by LAC 33:XV.41~~5~~6, shall not vent, release, or otherwise discharge airborne radioactive material to an ~~uncontrolled~~unrestricted area in concentrations ~~which~~that exceed the limits specified in LAC 33:XV.Chapter 4, Appendix A, Table II, except as authorized pursuant to LAC 33:XV.4~~1~~522.B or 4~~32~~61. For purposes of this ~~Paragraph~~Subsection, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to ~~uncontrolled~~unrestricted areas as far below these limits as is reasonably achievable. Records of intentional releases shall be maintained for two years for inspection by the division.

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:**

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

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

§1001. Purpose and Scope

This Chapter establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with division inspections of licensees or registrants to ascertain compliance with the provisions of the ~~A~~act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this ~~Part~~Chapter apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed or registered pursuant to ~~the regulations in~~ LAC 33:XV.Chapters 2 and 3.

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:**.

§1002. through §1010. ┼Reserved┼

§1011. Posting of Notices to Workers

A. Unless specifically provided otherwise by these regulations, each licensee or registrant shall post current copies of the following documents:

1. the regulations in this Chapter and LAC 33:XV. Chapter 4;

2. the license, certificate of registration, conditions or documents incorporated into the license by reference, and amendments thereto;

3. the operating procedures applicable to work under the license or registration;

4. any notice of violation involving radiological working conditions, proposed imposition of penalty or order issued pursuant to LAC 33:XV.Chapter 1, and any response from the

licensee or registrant.

B. If posting of a document specified in LAC 33:XV.1011.A.1, 2, or 3 is not practical, the licensee or registrant may post a notice ~~which~~that describes the document and states where it may be examined.

C. Form DRC-3, "Notice to Employees," shall be posted by each licensee or registrant as required by LAC 33:XV. Form DRC-3 will be furnished by the division on request.

D. Documents posted pursuant to LAC 33:XV.1011.A.4 shall be posted within five working days after receipt of the documents; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

E. Documents, notices, or forms posted pursuant to this Section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

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:**.

§1012. Instructions to Workers

~~All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area; shall be 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; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the Louisiana radiation regulations and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of the Louisiana Radiation regulations and licenses or unnecessary~~

~~exposure to radiation or radioactive material; shall be 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 shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to LAC 33:XV.1013. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.~~

A. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area.

B. All individuals working in or frequenting any portion of a restricted area shall be 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.

C. All individuals working in or frequenting any portion of a restricted area shall be 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 occurring in such areas.

D. All individuals working in or frequenting any portion of a restricted area shall be 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.

E. All individuals working in or frequenting any portion of a restricted area shall be 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.

F. All individuals working in or frequenting any portion of a restricted area shall be advised as to the radiation exposure reports that workers shall be furnished pursuant to LAC 33:XV.1013.

G. The extent of the instructions required by Subsections A through F of this Section shall be commensurate with potential radiological health protection problems in the restricted area.

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:**.

§1013. Notifications and Reports to Individuals

A. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this Section. The information reported shall include data and results obtained pursuant to the Louisiana ~~r~~Radiation Protection ~~r~~Regulations (LAC 33:XV), orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to ~~these regulations~~LAC 33:XV.4~~1~~076. Each notification and report shall~~:~~ be in writing; includ~~inge~~ appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions

of the Louisiana ~~r~~Radiation Protection ~~r~~Regulations, LAC 33:XV.Chapter 10. You should ~~preserve~~ retain this report for further reference."

~~B. At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to LAC 33:XV.441.A and C of these regulations.~~

B. Each licensee or registrant shall advise all workers annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to LAC 33:XV.~~451.A and C~~476.

~~C. At the request of a worker formerly engaged in work controlled by the licensee or registrant, each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or~~

~~registration in which the worker participated.~~

C. Each licensee or registrant shall furnish to each worker a report of the worker's exposure (mrem) to radiation or radioactive material upon termination of employment. Such report shall be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.

D. When a licensee or registrant is required pursuant to LAC 33:XV.4~~55~~87 to report to the division any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a 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.

E. At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving a radiation dose, or of a worker who while employed by another person, is terminating an assignment to work

involving a radiation dose in the licensee's facility in that calendar quarter, each licensee shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

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:**.

§1014. Presence of Representatives of Licensees or Registrants and of Workers During Inspection

A. Each licensee or registrant shall afford to the division, at all reasonable times, opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to ~~these regulations~~LAC 33:XV.

B. During an inspection, division inspectors may consult privately with workers as specified in LAC 33:XV.1015. The licensee or registrant, or his or her representative, may accompany division inspectors during other phases of an inspection.

* * *

D. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in ~~Section 1012~~LAC 33:XV.1012.

* * *

G. Notwithstanding the other provisions of this ~~s~~Section, division inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

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:**.

§1015. Consultation With Workers During Inspections

A. Division inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the Louisiana ~~r~~Radiation Protection ~~r~~Regulations (LAC 33:XV) and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

B. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition ~~which he~~that the worker has reason to believe may have contributed to or caused any violation of the ~~A~~act, ~~these regulations~~LAC 33:XV, license conditions, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of LAC 33:XV.1016.A.

C. The provisions of LAC 33:XV.1015.B shall not be

interpreted as authorization to disregard instructions pursuant to LAC 33:XV.1012.

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 13:569 (October, 1987), amended Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:**.

§1016. Requests by Workers for Inspections

A. Any worker or representative of workers ~~who believes~~ believing that a violation of the ~~A~~act, ~~these regulations~~LAC 33:XV, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the division. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the division no later than at the time of inspection except that, upon the request of the worker giving such notice, ~~he~~such worker's name and the names

of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the division, except for good cause shown.

B. If, upon receipt of such notice, the division determines that the complaint meets the requirements set forth in LAC 33:XV.1016.A and that there are reasonable grounds to believe that the alleged violation exists or has occurred, ~~it~~the division shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections performed pursuant to this Section need not be limited to matters referred to in the complaint.

C. No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under ~~these regulations~~LAC 33:XV or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of ~~himself~~such worker or others of any option afforded by this ~~Part.~~Chapter, or any applicable state or federal law or regulation.

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:**.

§1017. Inspections Not Warranted: Informal Review

~~A. If the division determines, with respect to a complaint filed under LAC 33:XV.1016, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the division shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the secretary which will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the secretary which will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the secretary may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering~~

~~all written or oral views presented, the secretary shall affirm, modify or reverse the determination of the division and furnish the complainant and the licensee or registrant a written notification of its decision and the reason therefor.~~

A. Notification to Complainant and Informal Review

1. If the division determines, with respect to a complaint filed under LAC 33:XV.1016, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists, is occurring, or has occurred, the division shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the administrative authority, who will provide the licensee or registrant with a copy of such statement by certified mail, return receipt requested, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the administrative authority that will provide the complainant with a copy of such statement by certified mail, return receipt requested.

2. Upon the request of the complainant, the administrative authority may hold an informal conference in which

the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the administrative authority shall affirm, modify, or reverse the determination of the division and furnish the complainant and the licensee or registrant a written notification of his or her decision and the reason therefor.

B. Requirements of LAC 33:XV.1016.A Not Met. If the division determines that an inspection is not warranted because the requirements of LAC 33:XV.1016.A have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of LAC 33:XV.1016.A.

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:**.

June 17, 2011

10 CFR PART 20

Please Note: The bracket ✌ [ ] ✌ around a compatibility category designation means that the Section may have been adopted elsewhere in a State rules and it is not necessary to adopt it again.

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1001	Purpose		D	N/A		
§20.1002	Scope		D	N/A		
§20.1003	Definitions					
	Absorbed Dose	102	A	No		
	Accelerator-produced radioactive material		H&S			
	Act		D	N/A		
	Activity	102	A	No		
	Adult	102	A	No		
	Airborne radioactive material	102	A	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Airborne Radioactivity area	102	A	No		
	Air-purifying respirator	403	B	No		
	ALARA	102	A	No		
	Annual Limit on Intake (ALI)	403	A	No		
	Assigned Protection Factor (APF)	403	B	No		
	Atmosphere-supplying respirator	403	B	No		
	Background Radiation	102	A	No		
	Bioassay (radio bioassay)	102	A	No		
	Byproduct material		H&S			
	Class	403	A	No		
	Collective Dose	102	A	No		
	Commission		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Committed dose equivalent	102	A	No		
	Committed effective dose equivalent	102	A	No		
	Constraint	403	C	No		
	Controlled Area	102	D	N/A		
	Critical group	403	B	No		
	Declared Pregnant Woman	403	A	No		
	Decommission	102	[C]	No		
	Deep-dose equivalent	102	A	No		
	Demand respirator	403	B	No		
	Department		D	N/A		
	Derived air concentration (DAC)	403	A	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Derived air concentration-hour (DAC-hour)	403	A	No		
	Disposable respirator	403	B	No		
	Distinguishable from background	102	B	No		
	Dose or radiation dose		D	N/A		
	Dose equivalent	102	A	No		
	Dosimetry processor		D	N/A		
	Effective dose equivalent	102	A	No		
	Embryo/fetus	102	A	No		
	Entrance or access point	102	C	No		
	Exposure		D	N/A		
	External dose		D	N/A		
	Extremity	102	A	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Filtering facepiece (dusk mask)	403	B	No		
	Fit factor	403	B	No		
	Fit test	403	B	No		
	Generally applicable environmental radiation standards	102	A- States with authority to regulate uranium mill activities (11e.(2) byproduct material)	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
			D- States without authority			
	Government agency		D	N/A		
	Gray	102	A	No		
	Helmet	403	B	No		
	High radiation area	102	A	No		
	Hood	403	B	No		
	Individual	102	A	No		
	Individual monitoring	102	A	No		
	Individual monitoring devices	102	C	No		
	Internal dose	102	A	No		
	Lens dose equivalent	102	A	No		
	License		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Licensed material		D	N/A		
	Licensee		D	N/A		
	Limits	102	A	No		
	Loose-fitting facepiece	403	B	No		
	Lost or missing licensed material	102	B	No		
	Member of the public	102	A	No		
	Minor	102	A	No		
	Monitoring	102	A	No		
	Nationally tracked source	102	B	No		
	Negative pressure respirator	403	B	No		
	Nonstochastic effect[1]	403	A	No		
	NRC		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Occupational Dose	102	A	No		
	Particle Accelerator		H&S			
	Person	102	[C]	No		
	Planned special exposure	403	D	N/A		
	Positive pressure respirator	403	B	No		
	Powered air-purifying respirator (PAPR)	403	B	No		
	Pressure demand respirator	403	B	No		
	Public dose	102	A	No		
	Qualitative fit test (QLFT)	403	B	No		
	Quality Factor	102	A	No		
	Quantitative fit test (QNFT)	403	B	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Quarter		D	N/A		
	Rad	102	A	No		
	Radiation	102	A	No		
	Radiation area	102	A	No		
	Reference man	403	A	No		
	Rem	102	A	No		
	Residual radioactivity	102	B	No		
	Respiratory protective device	403	C	No		
	Restricted area	102	A	No		
	Sanitary sewerage	403	A	No		
	Self-contained breathing apparatus (SCBA)	403	B	No		
	Shallow-dose equivalent	102	A	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Site boundary		D	N/A		
	Source Material	102	[A]	No		
	Special Nuclear Material	102	[A]	No		
	Stochastic effects[2]	403	A	No		
	Supplied-Air respirator (SAR) or airline respirator	403	B	No		
	Survey	102	A	No		
	Tight-fitting facepiece	403	B	No		
	Total Effective Dose Equivalent (TEDE)	102	A	No		
	Unrestricted Area	102	A	No		
	Uranium Fuel Cycle		D	N/A		
	User seal check (fit check)	403	B	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Very High Radiation Area	403	A	No		
	Waste	102	B	No		
	Week		D	N/A		
	Weighting factor	403	A	No		
	Whole body	102	A	No		
	Working level (WL)	102	A	No		
	Working level month (WLM)	102	A	No		
	Year	102	A	No		
§20.1004	Units of radiation dose	102	A	No		
§20.1005	Units of radioactivity	102	A	No		
§20.1006	Interpretations		D	N/A		
§20.1007	Communications		D	N/A		
§20.1008	Implementation		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1009	Information collection requirements: OMB approval		D	N/A		
§20.1101	Radiation protection programs		H&S			
§20.1101 (d)	Radiation protection programs	406.D	C	No		
§20.1201	Occupational dose limits for adults	410	A	No		
§20.1202	Compliance with requirements for summation of external and internal doses	411	A	No		
§20.1203	Determination of external dose from airborne radioactive material	412	A	No		
§20.1204	Determination of internal exposure	413	A	No		
§20.1205	Reserved					

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1206	Planned special exposures		D	N/A		
§20.1207	Occupation dose limits for minors	416	A	No		
§20.1208	Dose equivalent to an Embryo/fetus	417	A	No		
§20.1301 (a)(b)(c)	Dose limits for individual members of the public	421	A	No		
§20.1301 (d)	Dose limits for individual members of the public	421	C	No		
§20.1301 (e)	Dose limits for individual members of the public	421	A for States with authority to regulate U-mill activities	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
			D for States without authority			
§20.1301 (f)	Dose limits for individual members of the public		D	N/A		
§20.1302 (a)(b)	Compliance with dose limits for individual members of the public		H&S			
§20.1302 (c)	Compliance with dose limits for individual members of the public		D	N/A		
§20.1401	General provisions and scope	332	C	No		
§20.1402	Radiological criteria for unrestricted use	332	C	No		
§20.1403	Criteria for license termination under restricted conditions	332	C	No		
§20.1404	Alternate criteria for license termination	332	C	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1405	Public notification and public participation	332	C	No		
§20.1406(a)	Minimization of contamination	332	C	No		
§20.1406(b)	Minimization of contamination		NRC			
§20.1501	General	430	H&S			
§20.1502	Conditions requiring individual monitoring of external and internal occupational dose	431	H&S			
§20.1601	Control of access to high radiation areas	436	H&S			
§20.1602	Control of access to very high radiation areas	437	H&S			
§20.1701	Use of process or other engineering controls	440	H&S			
§20.1702	Use of other controls	441	H&S			

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1703	Use of individual respiratory protection equipment	442	H&S			
§20.1704	Further restrictions on the use of respiratory protection equipment		D	N/A		
§20.1705	Application for use of higher assigned protection factors	443	B	No		
§20.1801	Security of stored material	445	H&S			
§20.1802	Control of material not in storage	445	H&S			
§20.1901	Caution signs	450	A	No		
§20.1902	Posting requirements	451	A	No		
§20.1903	Exceptions to posting requirements		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.1904	Labeling containers	453	A	No		
§20.1905 (a) – (f)	Exceptions to labeling requirements	454	A	No		
§20.1905 (g)	Exceptions to labeling requirements		NRC			
§20.1906	Procedures for receiving and opening packages	455	H&S			
§20.2001	General requirements (Waste Disposal)	460	C	No		
§20.2002	Method for obtaining approval of proposed disposal procedures		D	N/A		
§20.2003 (a)(1)	Disposal by release into sanitary sewerage	462	H&S	No		
§20.2003 (a)(2)&(a)(3)	Disposal by release into sanitary sewerage	462	A	No		
§20.2003	Disposal by release into	462	C	No		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
(a)(4)	sanitary sewerage					
§20.2003 (b)	Disposal by release into sanitary sewerage		D	N/A		
§20.2004	Treatment or disposal by incineration		D	N/A		
§20.2005	Disposal of specific wastes		D	N/A		
§20.2006	Transfer for disposal and manifests	465	B	No		
§20.2007	Compliance with environmental and health protection regulations		D	N/A		
§20.2008	Disposal of certain byproduct material	465	B	No		
§20.2101	General provisions	470	C	No		
§20.2102	Records of radiation protection programs		D	N/A		
§20.2103	Records of surveys		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.2104	Determination of prior occupational dose		H&S-for States who adopt "planned special exposure" D-for those who do not			
§20.2105	Records of planned special exposures		D	N/A		
§20.2106 (a)&(e)	Records of individual monitoring results	476	C	No		
§20.2106 (b)(c)(d)(f)	Records of individual monitoring results		D	N/A		
§20.2107	Records of Dose to individual members of the Public		D	N/A		
§20.2108	Records of Waste Disposal		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
§20.2110	Form of Records		D	N/A		
§20.2201 (a)(b)(d)(e)	Reports of theft or loss of licensed material	485	C	No		
§20.2201 (c)	Reports of theft or loss of licensed material		D	N/A		
§20.2202 (a)(b)(c)(d)	Notification of Incidents	486	C	No		
§20.2202 (e)	Notification of Incidents		D	N/A		
§20.2203 (a)(b)	Reports of exposures, etc, exceeding the limits.	487	C	No		
§20.2203 (c)	Reports of exposures, etc, exceeding the limits.		NRC			
§20.2203 (d)	Reports of exposures, etc, exceeding the limits.		D	N/A		
§20.2204	Reports of Planned special exposures	488	H&S-for States who			

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
			adopt "planned special exposure" D-for those who do not			
§20.2205	Reports to individuals of exceeding dose limits	491	C	No		
§20.2206 (a)(1), (a)(3), (a)(4), (a)(5)	Reports of Individuals Monitoring		NRC			
§20.2206 (a)(2), (a)(6), (a)(7), (b) &(c)	Reports of Individuals Monitoring		D	N/A		
§20.2207	Reports of transactions involving nationally tracked sources	493	B	No		
§20.2301	Applications for		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
	Exemptions					
§20.2302	Additional Requirements		D	N/A		
§20.2401	Violations		D	N/A		
§20.2402	Criminal Penalties		D	N/A		
Appendix A	Protection Factors for Respirators	499. App. A	B	No		
Appendix B (Tables 1,2, & 3)	Annual Limits on Intake (ALIs), Derived Air Concentrations (DACs), of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage	499. App. B	A	No		
Appendix C	Quantities of licensed materials requiring labeling	499. App. C	A	No		
Appendix D	United States Nuclear Regulatory Commission Offices		D	N/A		

NRC Regulation Section	Section Title	State Section	Compatibility Category	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not was a Comment Generated
Appendix E	Nationally tracked source thresholds	399. App.G	B	No		
Appendix F	Reserved					
Appendix G	Requirements for Low-level radioactive waste intended for disposal at land disposal facilities and manifests	499. App. D	B	No		
Appendix G Forms 540, 540A, 541, 542, & 542A	Requirements for Low-level radioactive waste intended for disposal at land disposal facilities and manifests		D	N/A		

[1] The tern "Deterministic effect" if defined essentially identical to "Nonstochastic effect" is an acceptable substitute.
[2] The term "Probabilistic effect" if defined essentially identical to "Stochastic effect" is an acceptable substitute.

FILE G

Title 33

ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 3. Licensing of Radioactive Material

§341. Reporting Requirements for General and Specific Licensees

A. Immediate Report. Each licensee shall notify the division as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

B. Twenty-four Hour Report. Each licensee shall notify the division within 24 hours after the discovery of any of the following events involving licensed material:

1. an unplanned contamination event that:

a. requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

b. involves a quantity of material greater than five times the lowest annual limit on intake specified in LAC 33:XV.Chapter 4, Appendix B, for the material; and

c. requires access to the area to be restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination;

2. an event in which equipment is disabled or fails to function as designed when:

a. the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

b. the equipment is required to be available and operable when it is disabled or fails to function; and

c. no redundant equipment is available and operable to perform the required safety function;

3. an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; or

4. an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

a. the quantity of material involved is greater than five times the lowest annual limit on intake specified in LAC 33:XV.Chapter 4, Appendix B, for the material; and

b. the damage affects the integrity of the licensed material or its container.

C. Preparation and Submission of Reports. Reports made by licensees in response to the requirements of LAC 33:XV.341 must be made as follows:

1. licensees shall make reports required by LAC 33:XV.341.A and B by telephone to the division. To the extent that the information is available at the time of notification, the information provided in these reports must include:

a. the caller's name and call-back telephone number;

b. a description of the event, including date and time;

c. the exact location of the event;

d. the isotopes, quantities, and chemical and physical form of the licensed material involved; and

e. any personnel radiation exposure data available; and

2. each licensee who makes a report required by LAC 33:XV.341.A or B shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the division. The reports must include the following:

a. a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

b. the exact location of the event;

c. the isotopes, quantities, and chemical and physical form of the licensed material involved;

d. date and time of the event;

e. corrective actions taken or planned and the results of any evaluations or assessments; and

f. the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

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 **.

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:

* * *

[See Prior Text In 1 - 3.i]

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~~within thirty days of occurrence~~;

* * *

[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 **

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 7. Use of Radionuclides in the Healing Arts

§777. Quality Management Program

* * *
[See Prior Text In A - A.5]

B. The licensee shall:

1. develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

a. a representative sample of patient administrations; ~~and~~

b. ~~all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months; and~~ all recordable events; and

c. ~~all recordable events;~~ all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months.

* * *
[See Prior Text In B.2 - 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**

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 20. Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies

Subchapter D. Notification

§2051. Notification of Incidents, Abandonment, and Lost Sources

A. ~~Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Chapter 4 of these regulations.~~ The licensee shall immediately notify the division by telephone and subsequently within ~~three~~30 days by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the release of licensed materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

* * *

[See Prior Text In B - D.2.h]

E. The licensee shall notify the division of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation or radioactive materials, and certain other accidents as required by LAC 33:XV.341, 485, 486, and 487.

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**

Notification of Incidents
(56 FR 40757, 56 FR 64980) RATS ID 1991-4 Effective 10/15/91

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§20.2202	Notification of Incidents	486	C	Please refer to section 20.2202 (a)-(d) for the current wording of the rule.	No		
§20.2202 (e)	Notification of Incidents		D	The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under §20.2204	N/A		
§30.50	Notification of Incidents	486	C	Please refer to section 30.50 for the current wording of the rule.	No		
§30.50 (c)(3)	Notification of Incidents		D	Please refer to section 30.50 for the current wording of the rule.	N/A		
§40.60	Reporting Requirements	486	C	Please refer to section 40.60 for the current wording of the rule.	No		
§40.60 (c)(3)	Reporting Requirements		D	Please refer to section 40.60 for the current wording of the rule.	N/A		

§70.50	Reporting Requirements	486	C	Please refer to section 70.50 for the current wording of the rule.	No		
§70.50 (c)(3)	Reporting Requirements		D	Please refer to section 70.50 for the current wording of the rule.	N/A		

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.

****
[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 licensed practitioner of the healing arts who is identified as an authorized user on an agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material~~ 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.

****
[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.

****

[See Prior Text]

*High-r*Radiation Area ~~any area accessible to individuals in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems (1 millisievert)~~ 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.

***

[See Prior Text]

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

***

[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 ~~patient~~ individual or wrong radiopharmaceutical; or

***

[See Prior Text in 1.b]

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

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

***

[See Prior Text in 2.b—3]

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

***

[See Prior Text in 3.b—4]

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

***

[See Prior Text in 4.b—5]

a. involving the wrong ~~patient~~ 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);

****

[See Prior Text in 5.b—6]

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

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

****

[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 ~~or not the sources of radiation are~~ in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: from background radiation, ~~as a patient from medical practices~~ 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.

****

[See Prior Text]

Pharmacist—any individual licensed by ~~the Louisiana Board of Pharmacy to operate a pharmacy, all as provided in R.S. 37:1171 et seq~~ a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

****

[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.

****

[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 ~~as a patient from medical practices~~ 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.

****

[See Prior Text]

~~any area accessible to individuals in which there exists radiation at such levels that a major portion of the body could receive in any~~ an area, accessible to individuals, in which radiation levels could result in an dose in excess of 100 millirems (~~1~~ one millisievert).

[See Prior Text]

Radiological Physicist

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

[See Prior Text in 2—3]

Recordable Event—

****

[See Prior Text in 1—4]

administered dose ~~is 15 percent greater than~~ exceeds the weekly prescribed by 15 percent or more; or

dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

[See Prior Text]

Restricted Area ~~*controlled area)*~~ an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against A restricted area does residential building may be set apart as a restricted area.

****

Survey—an evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such measurements of levels of radiation or concentrations of radioactive materials present.

****

[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.

~~*Visiting Authorized User*—an authorized user who is not identified on the license of the licensee being visited.~~

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.

****

[See Prior Text]

Working Level (WL)—any combination of short-lived radon~~-222~~ daughters~~, polonium-217,~~ (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 ~~1~~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.

****

[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:

****

[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

Chapter 3. Licensing of Radioactive Material

§304. Radioactive Material Other Than Source Material

[See Prior Text in A—C.4]

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

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 owns, or acquires capsules containing 37 kBq (1µCi) carbon-14 urea each (allowing for nominal variation that may occur during the manufacturing

b. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license

c. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution with LAC 33:XV.328.K.

d. Nothing in this Section relieves persons from complying with receipt, administration, and use of drugs.

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

§325. General Requirements for the Issuance of Specific Licenses

***

b. submit a certification that financial assurance arrangement for decommissioning has been provided in the amount prescribed by ~~LAC 33:XV.325.~~D.4 using one of the methods described in Subsection ~~LAC 33:XV.325.~~ D.6. For an applicant, this certification may state that the appropriate assurance will be obtained after receipt of licensed material. If the applicant defers execution of the original of the financial instrument obtained to satisfy the requirements of Subsection D.6 of this Section shall be submitted to the division before financial instrument, the applicant shall submit to the division, ~~A~~s part of requirements of Subsection ~~LAC 33:XV.325.~~D.6 ~~is to be~~.

****

[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 ~~LAC 33:XV.325.~~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 ~~LAC 33:XV.325.~~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.

****

[See Prior Text in D.4–4.c]

5. Each decommissioning funding plan ~~must~~ shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection ~~LAC 33:XV.325.~~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.

****

[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. ~~Reserved~~ 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. ~~Licensing the Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses~~ 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 ~~and distribute radiopharmaceuticals containing radioactive material~~, prepare, or transfer for commercial distribution radioactive drugs for use by persons ~~licensed pursuant to this Chapter for the uses listed in LAC 33:XV.330, 332, and 336~~ authorized in accordance with LAC 33:XV.Chapter 7 ~~will~~ 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. ~~the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the U.S. Food and Drug Administration (FDA) or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or~~ registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

ii. ~~the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.~~ 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 affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label affixed to each package, or the leaflet or brochure that accompanies each package, contains a statement that the radiopharmaceutical is licensed by the administrative authority for distribution to persons licensed for medical use pursuant to LAC 33:XV.330, 332, and 336 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, any other agreement state, or a licensing state; and~~ 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. ~~Licensing the Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material~~ 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. Although the division does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his or her reagent kits approved by the division for use by persons licensed pursuant to LAC 33:XV.332 of these regulations may submit the pertinent information specified in LAC 33:XV.328.K.~~

~~a. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this Chapter for the uses listed in LAC 33:XV.332 will be approved if the following conditions are met:~~

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

~~ii. the applicant submits evidence that:~~

~~(a). the generator or reagent kit is to be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Act, such as a new drug application (NDA) approved by the U.S. Food and Drug Administration (FDA) or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or~~

~~(b). the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.~~

~~iii. the applicant submits information on the radionuclide; chemical and physical form; packaging; including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;~~

~~iv. the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and~~

~~v. the label affixed to the generator or reagent kit, or the leaflet or brochure that accompanies the generator or reagent kit, contains:~~

~~(a). adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator, or processing radioactive material with the reagent kit; and~~

~~(b). a statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the administrative authority pursuant to LAC 33:XV.332 of these regulations or under equivalent~~

~~licenses of the U.S. Nuclear Regulatory Commission, any other agreement state, or a licensing state. The labels, leaflets, or brochures required by this Section are in addition to the labeling required by the FDA, and they may be separate from, or, with the approval of the FDA, may be combined with the labeling required by the FDA.~~

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; ~~and~~

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:**.

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 ~~of patients to radiation for the purpose of medical diagnosis or therapy~~ 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 ~~may enter the licensee's or registrant's restricted area and~~ 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

accordance with LAC 33:XV.462 ;

2. the dose in any unrestricted area from external sources, exclusive and released in accordance with LAC 33:XV.725, does not exceed 0.02 mSv

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[See Prior Text in A.3-E]

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Nuclear Energy Division, LR 13:569 (October 1987), amended Office of Air

(November 1993), LR 22:970 (October 1996), amended LR 24:**.

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

§445. Security of Stored Sources of Radiation

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B. The licensee or registrant shall maintain constant surveillance or use devices or administrative procedures to prevent unauthorized use of licensed ~~an~~ unrestricted area and that is not in storage.

[See Prior Text in C—D]

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

Office of Air Quality and Radiation Protection, Radiation Protection Division, LR 19:1421 (November 1993), LR 22:972 (October 1996), amended LR 24:**.

§452. Exceptions to Posting Requirements

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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, ~~requirements of~~ control in accordance with LAC 33:XV.725 and 745 ~~———~~.

[3]Retrofit shall not be required for locations within facilities where requirements of 5 mSv (0.5 rem) in a year.

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[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 ~~Appendix~~ Appendices D and E of this Chapter are designed to: control transfers of low-level radioactive waste ~~intended for disposal at~~ 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 ~~as specified in Subsection A of~~ in accordance with Appendix D of this Chapter.

C. Each shipment manifest shall include a certification by the waste generator ~~as specified in Subsection B of~~ 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 ~~Subsection C of~~ 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, 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. The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1 percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in Subsection A of Appendix E shall be clearly identified as such in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest required by this Paragraph may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this Appendix may be legible carbon copies or legible photocopies.~~

~~B. Certification. The waste generator shall include in the shipment manifest a certification 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. An authorized representative of the waste generator shall sign and date the manifest.~~

~~C. Control and Tracking~~

~~1. Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in Paragraph 1.a through h of this Subsection. Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of Paragraph 1.d through h of this Subsection. A licensee shall:~~

~~a. prepare all wastes so that the waste is classified according to Subsection A of Appendix E and meets the waste characteristics requirements in Subsection B of Appendix E;~~

~~b. label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Subsection A of Appendix E;~~

~~c. conduct a quality control program to ensure compliance with Subsections A and B of Appendix E; the program shall include management evaluation of audits;~~

~~d. prepare shipping manifests to meet the requirements of Subsections A and B of this Appendix;~~

~~e. forward a copy of the manifest to the intended recipient at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;~~

~~f. include one copy of the manifest with the shipment;~~

~~g. retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by LAC~~

~~33:XV.340; and~~

~~h. for any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Subsection C.5 of this Appendix.~~

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

~~a. acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;~~

~~b. prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in Subsection A of this Appendix. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;~~

~~c. forward a copy of the new manifest to the land disposal facility operator at the time of shipment;~~

~~d. include the new manifest with the shipment to the disposal site;~~

~~e. retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by LAC 33:XV.340, and retain information from generator manifest until disposition is authorized by the division; and~~

~~f. for any shipments or any portion of a shipment for which acknowledgement of receipt is not received within the times set forth in this Appendix, conduct an investigation in accordance with Subsection C.5 of this Appendix.~~

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

~~a. acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;~~

~~b. prepare a new manifest that meets the requirements of Subsections A and B of this Appendix. Preparation of the new manifest reflects that the processor is responsible for the waste;~~

~~c. prepare all wastes so that the waste is classified according to Subsection A of Appendix E and meets the waste characteristics requirements in Subsection B of Appendix E;~~

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

~~e. conduct a quality control program to ensure compliance with Subsections A and B of Appendix E. The program shall include management evaluation of audits;~~

~~f. forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;~~

~~g. include the new manifest with the shipment;~~

~~h. retain copies of original manifests and new manifests and documentation of acknowledgement of receipt as the record of transfer of licensed material required by LAC 33:XV.340; and~~

~~I. for any shipment or portion of a shipment for which acknowledgement is not received within the times set forth in this Appendix,~~

~~conduct an investigation in accordance with Subsection C.5 of this Appendix.~~

~~4. The land disposal facility operator shall:~~
~~a. acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;~~
~~b. maintain copies of all completed manifests or equivalent documentation until the division authorizes their disposition; and~~
~~c. notify the shipper (i.e. the generator, collector, or processor) and the division when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.~~

~~5. Any shipment or portion 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 to the division. 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.~~

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 into 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:**.

ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Operations

§550. Performance Requirements for Radiography Equipment

used in industrial operations must meet the following minimum criteria:

1. each radiographic exposure device and all associated equipment ~~———~~ shall (ANSI) N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued . Engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on 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]

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 and

k. notwithstanding Subsection A.1, 4, and 5 of this Section, 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 radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

[See Prior Text in 4—5]

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

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

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~~ of these regulations~~. 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~~ of these regulations~~. 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 ~~pursuant to these regulations~~ 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~~, except a visiting authorized user described in LAC 33:XV.710,~~ 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 ~~notify~~ 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 ~~in writing within~~ 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. ~~when an authorized user, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license.~~

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 ~~the~~ 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. ~~Visiting Authorized User~~ Repealed.

~~A. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for a period not to exceed 60 days in any calendar year if:~~

~~1. the visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;~~

~~2. the licensee has a copy of an agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; and~~

~~3. only those procedures for which the visiting authorized user is specifically authorized by an agreement state, licensing state, or U.S. Nuclear Regulatory Commission license are performed by that individual.~~

~~B. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in LAC 33:XV.710.A.~~

~~C. A licensee shall retain copies of the records specified in LAC 33:XV.710.A for five years from the date of the last visit.~~

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 ~~must~~ 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 ~~patient~~ individual who received the administration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the ~~patient~~ individual, or the ~~patient's~~ individual's responsible relative or guardian (this person will be subsequently referred to as "the ~~patient~~ individual" in this Section), and if not, why not, and if the ~~patient~~ individual was notified, what information was provided to the ~~patient~~ individual. The report ~~must~~ shall not include the ~~patient's~~ individual's name or other information that could lead to identification of the ~~patient~~ 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 ~~patient~~ individual ~~of~~ 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 ~~patient~~ individual or that, based on medical judgement, telling the ~~patient~~ individual would be harmful. The licensee is not required to notify the ~~patient~~ individual without first consulting the referring physician. If the referring physician or ~~patient~~ individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the ~~patient~~ individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the ~~patient~~ individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification~~.~~;

4. if the ~~patient~~ individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the ~~patient~~ 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 ~~patient~~ 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 ~~must~~ shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the ~~patient~~ individual who received the misadministration, and the ~~patient's~~ individual's referring physician), the ~~patient's~~ 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 ~~patient~~ 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, ~~patients~~ the individual, or the ~~patient's~~ 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 ~~pursuant to~~ in accordance with these regulations or the equivalent regulations of another agreement state, a licensing state, or the ~~U.S.~~ 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 ~~Calibrators~~

A. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the ~~amount of~~ activity ~~administered to each patient~~ 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.

~~C.~~D. Retain a record of the assays required by ~~LAC 33:XV.717.A and B~~ 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 ~~Patients~~ Individuals Containing Radiopharmaceuticals or Permanent Implants

A. A licensee ~~shall not~~ 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). ~~confinement for medical care any patient administered a radiopharmaceutical until either:~~

~~1. the dose rate from the patient is less than 5 milliroentgens (50 μSv) per hour at a distance of 1 meter; or~~

~~2. the activity in the patient is less than 30 millicuries (1.11 GBq).~~

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: ~~not authorize the release from confinement for medical care of any patient administered a permanent implant until the dose rate from the patient is less than 5 milliroentgens (50 μSv) per hour at a distance of 1 meter.~~

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 ~~LAC 33:XV.736.~~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. Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient .~~

~~7.~~ 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 ~~must~~ shall not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

~~8.~~ 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 ~~must~~ shall be performed within three days after administering the dosage, and records ~~must~~ 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 ~~must~~ 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 ~~do the following~~:

1. ~~Do not place~~ not quarter the patient or human research subject in the same room ~~with a patient~~ as an individual who is not receiving radiation therapy; ~~unless the licensee can demonstrate compliance with the requirement of LAC 33:XV.415.A of these regulations at a distance of 1 meter from the implant.~~

2. ~~P~~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. ~~A~~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. ~~P~~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.

~~5. Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.~~

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 ~~Each time~~ brachytherapy sources ~~are returned~~ to an area of storage from ~~an~~ the area of use, ~~the licensee shall~~ 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 ~~LAC 33:XV.745.~~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 ~~1~~ 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 ~~LAC 33:XV.764~~ 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; ~~or~~
   e. Board of Pharmaceutical Specialties in Nuclear Pharmacy ~~or Science;~~ ~~or~~
   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~~,~~;
   ~~e~~d. radiation biology~~,~~;
   ~~f~~e. radiopharmaceutical chemistry~~,~~; and
   ~~g~~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 ~~U.S.~~ 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.

~~**§764**~~ B. ~~Training for~~ Experienced Radiation Safety Officer. An individual identified as a radiation safety officer on a division, agreement state, licensing state, or ~~U.S.~~ 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 ~~LAC 33:XV.763~~ Subsection A of this Section.

~~§765~~ C. ~~Training for~~ Uptake, Dilution, or Excretion Studies. Except as provided in ~~LAC 33:XV.773 and 774~~ 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; ~~or~~
   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 ~~must~~ 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 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 ~~LAC 33:XV.765.A.1.b.~~ Subsection C.2.b of this Section.

~~§766~~ D. ~~Training for~~ Imaging and Localization Studies. Except as provided in ~~LAC 33:XV.773 or 774~~ 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; ~~or~~
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 ~~LAC 33:XV.766.A.2~~ Subsection D.2 of this Section.

~~§767~~ E. ~~Training for~~ Therapeutic Use of Radiopharmaceuticals. Except as provided in ~~LAC 33:XV.773~~ 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; ~~or~~
   b. the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; ~~or~~
   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.

~~§768~~ F. ~~Training for~~ Therapeutic Use of Brachytherapy Sources. Except as provided in ~~LAC 33:XV.773~~ 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.

~~**§769**~~ G. ~~Training for~~ Ophthalmic Use of Strontium-90. Except as provided in ~~LAC 33:XV.773~~ 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.

~~§770~~ H. ~~Training for~~ Use of Sealed Sources for Diagnosis. Except as provided in ~~LAC 33:XV.773~~ 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; ~~or~~

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~~ eight 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.

~~§771~~ I. ~~Training for~~ Teletherapy. Except as provided in ~~LAC 33:XV.773~~ 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.

~~§772~~ J. ~~Training for~~ Teletherapy Physicist. A teletherapy physicist shall meet the criteria ~~defined~~ 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.

~~**§773**~~ M. ~~Training for~~ 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 ~~LAC 33:XV.763 through 775~~ this Section.

~~**§774**~~ N. Physician Training in a Three-~~m~~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 ~~LAC 33:XV.765 or 766~~ Subsection C or D of this Section.

~~**§775**~~ O. Recentness of Training. The training and experience specified in ~~LAC 33:XV.763 through 772~~ 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:

~~A.~~1. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace~~.~~;

~~B.~~2. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ 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~~.~~;

~~C.~~3. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ 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~~.~~;

~~D.~~4. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ 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~~.~~;

~~E.~~5. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ 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

~~F.~~6. ~~All individuals working in or frequenting any portion of a restricted area shall be~~ advised as to the radiation exposure reports that workers shall be furnished ~~pursuant to~~ in accordance with LAC 33:XV.1013.

~~G.~~B. The extent of the instructions required by Subsection~~s~~ A ~~-F~~ 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 ~~pursuant to~~ 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 ~~LAC 33:XV.1333.~~ Subsections A – C of this Section, copies of records of the location and the quantity of radioactive wastes contained in the disposal site ~~must~~ 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 ~~in~~ of disposal at the disposal site, the ~~condition~~ 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, ~~pursuant to~~ 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 ~~predicted~~ expected in the materials previously viewed as part of the licensing action, the report ~~must~~ 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 shall 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

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 µCi) 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 by 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:**.

MEMORANDUM

To: Tim Knight, Administrator
Investigations and Regulation Development Division

From: Ronnie Wascom, Administrator
Radiation Protection Division

Subject: Technical Amendments of Proposed Rule Log # NE020*

Date: October 23, 1998

There are two technical amendments to be made in Proposed Rule Log # NE020*. Both amendments are of typographical errors, and are detailed as follows:

1) LAC 33:XV.763.H.2 -- training requirement corrected to read 8 hours, instead of 80 hours. This typographical error was noticed by the Nuclear Regulatory Commission regulation amendment review as out of compliance with their corresponding regulation, 10 CFR 35.950 (first published in 51 FR 36951, Oct. 16, 1986, then amended at 59 FR 61786, Dec. 2, 1994).

2) LAC 33:1743.A -- parenthetical value in the middle of the paragraph corrected from 0.005 Ci to 0.005 μCi. This was a typographical error.

In all other respects, Proposed Rule with Technical Amendments # NE020* is identical to Proposed Rule # NE020*.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
Chapter 4, App. D	10 CFR 20 App. G	60 FR 15649, 60 FR 25983	Switched all low-level waste shipping manifests to NRC forms, allowing for electronic media. This required total rewrite of the Appendix. Added authority and historical notes as required by Regulation Development.
§102	§35.961	59 FR 61767, 59 FR 65243	Added qualification in definition of "Radiological Physicist" to comply with new certification allowance for teletherapy physicists (§772).
§102	§30.4	59 FR 36026	Added definition of "Principal Activities," for use in amendments to section §332.
§102	§35.2	59 FR 61767, 59 FR 65243	Deleted definition of "Visiting Authorized User," added definition of "Authorized Nuclear Pharmacist," and amended definitions of "Authorized User," "Medical Use," "Misadministration," "Pharmacist," "Recordable Event," and "Written Directive."
§102	§20.1003	60 FR 36038, 60 FR 48623, 62 FR 4120	Amended definitions of "Occupational Dose," and "Public Dose." Subsequently reamended in accordance with 60 FR 48623 and 62 FR 4120.
§102	§20.1003	N/A	Inserted definitions for "Controlled Area," and amended definitions of "Restricted Area," "High Radiation Area," "Radiation Area," "Survey,", and "Working Level (WL)," to conform to NRC requirements stipulated in their 1995 review of our 10 CFR 20 equivalent.
§102	§35.2	60 FR 48623	Amended the definition of "Misadministration" by removing the term "patient" and substituting the term "individual."
§304	§30.21	62 FR 63634	Created a new section named §304.C.5, and inserted 10 CFR 30.21, "Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans."
§325	§30.35	60 FR 38235	Clarified decommissioning funding requirements.
§326	§36.13	58 FR 7715	Added new subsection regarding specific licenses for irradiators, in accordance with SSRCR Part Q, derived from 10 CFR 36 (see Chapter 17).

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§328	§32.72	59 FR 61767, 59 FR 652436 0 FR 322	Amended §328.J, for licensing of radioactive drugs, adding nuclear pharmacy provisions.
§328	§32.73	59 FR 61767, 59 FR 65243	Deleted §328.K, "Licensing the Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material."
§328	§32.21	62 FR 63634	Inserted 10 CFR 32.21, "License Requirements for the Manufacture and Distribution of Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans," into §328.K, which had been deleted in accordance with 59 FR 61767.
§332	§30.35 §30.36	59 FR 36026, 60 FR 38235	Added new paragraphs and amended others to include Timeliness in Decommissioning and Decommissioning Funding requirements.
§402	§20.1002	60 FR 48623, 62 FR 4120	Amended the "Scope" section of the General Provisions of the Standards for Protection Against Radiation to include the new concept of "medical administration," and to clarify the meaning of "sources of radiation." Added provision regarding exposure to released patients.
§414	§20.2104	60 FR 36038	Removed the phrase, " who may enter the licensee's or registrant's restricted area," from description of individuals for whom a licensee must determine a prior occupational dose.
§421	§20.1301	60 FR 48623, 62 FR 4120	Added a phrase to exclude background, medical administration, and research dose contributions, and exposure to released patients from public TEDE.
§445	§20.1802	N/A	Added stipulation that unauthorized use of materials in controlled areas, as well as in unrestricted areas, needs to be prevented. As per 10 CFR 20 review.
§452	§20.1903	62 FR 4120	Changed language in room posting exemption to clarify patient release from licensee control.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§465	§20.2006	60 FR 15649, 60 FR 25983	Added clarifying phrase to description of waste transfers. NRC has many changes to this section regarding grandfathering of applicable appendices, but none apply now that the due date for this reg has passed.
§470	§20.2101	60 FR 15649, 60 FR 25983	Required that all low-level waste shipment manifests be in SI units.
§550	§34.20	60 FR 28323	Added a sentence in §550.A.1 and a new section, §550.A.3.k, that relax the unreasonably rigid ANSI test requirements on cameras.
§701	§35.7	59 FR 61767, 59 FR 65243	Added sentence to end of §701, "Purpose and Scope."
§702	§35.11 §35.15	59 FR 61767, 59 FR 65243	Amended §702.A, and added §702.C and D, with nuclear pharmacy provisions and broad scope exemptions.
§703	§35.13 §35.6	59 FR 61767, 59 FR 65243	Revised the "License Amendments" section to include nuclear pharmacy and broad scope provisions, and provisions for research on human subjects.
§704	§35.14	59 FR 61767, 59 FR 65243	Revised "Notifications" section of Chap 7 to comply with NRC changes.
§707	§35.22	59 FR 61767, 59 FR 65243	Amended section on Radiation Safety Committee, mostly to include nuclear pharmacy provisions.
§709	§35.25	59 FR 61767, 59 FR 65243	Amended "Supervision" section, adding Nuclear pharmacy provisions.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§710	§35.27	59 FR 61767, 59 FR 65243	Removed entire section regarding "Visiting Authorized User."
§712	§35.33	60 FR 48623, 59 FR 61767, 59 FR 65243	Amended the section by removing the term "patient" and substituting the word "individual," and clarified language by deleting one sentence and inserting another in §712.A.2. 60 FR changes supersede 59 FR changes.
§713	§35.49	59 FR 61767, 59 FR 65243	Amended to explicitly include sealed sources and devices.
§715	§35.52	59 FR 61767, 59 FR 65243	Changed the Section title and added Subsection F., covering provisions regarding instruments to measure dosages of alpha- or beta- emitting radionuclides.
§715	§35.50	59 FR 61767, 59 FR 65243	Amended 1st paragraph to make clear that measurement had to be performed *before* administration, and to include human research subject provision. Other parts of this section are already in compliance.
§717	§35.53	59 FR 61767, 59 FR 65243	Added new section C and relettered section, to include measurement of alpha- and beta- emitters.
§720	§35.60	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§721	§35.60	59 FR 61767, 59 FR 65243	Amended to include human research subjects.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§725	§35.75	59 FR 61767, 59 FR 65243, 62 FR 4120	Amended to include human research subjects: entirely superseded by changes in 62 FR 4120, which is a total rewrite of the section, including breast-feeding requirements.
§729	§35.100	59 FR 61767, 59 FR 65243	Inserted nuclear pharmacy provisions.
§731	§35.200	59 FR 61767, 59 FR 65243	Inserted nuclear pharmacy provisions.
§735	§35.300	59 FR 61767, 59 FR 65243	Inserted nuclear pharmacy provisions.
§736	§35.310	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§737	§35.315	59 FR 61767, 59 FR 65243, 62 FR 4120	Amended to include human research subjects. Paragraph A.6, regarding patient release requirements, is removed.
§742	§35.410	59 FR 61767, 59 FR 65243	Amended to include human research subjects.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§743	§35.415	59 FR 61767, 59 FR 65243 62 FR 4120	Amended to include human research subjects. Paragraph A.5, regarding patient release requirements, is removed, and language in introduction and paragraph A.1 is slightly modified to include new patient release guidelines.
§744	§35.406	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§745	§35.404	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§750	§35.610	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§753	§35.615	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§754	§35.615	59 FR 61767, 59 FR 65243	Amended to include human research subjects.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§763	Training sections of Part 35	59 FR 61767, 59 FR 65243	Renumbered several sections(all involving training) and incorporated them as subsections in §763. This was necessary to make room for NRC insertions. The sections involved are as follows: BEFORE/NOW §763 / 763.A §764 / 763.B §765 / 763.C §766 / 763.D §767 / 763.E §768 / 763.F §769 / 763.G §770 / 763.H §771 / 763.I §772 / 763.J §773 / 763.M §774 / 763.N §775 / 763.O
§763	§35.980	59 FR 61767, 59 FR 65243	Inserted nuclear pharmacist training requirements as Subsection K.
§763	§35.981	59 FR 61767, 59 FR 65243	Inserted experienced nuclear pharmacist training requirements as Subsection L.
§763	§35.900	59 FR 61767, 59 FR 65243	Added new qualifying certifications for Radiation Safety Officers in nuclear medicine. Redesignated section as Subsection §763.A.
§765	§35.910	59 FR 61767, 59 FR 65243	Added new qualifying certification for training in nuclear medicine, and amended to include human research subjects. Redesignated section as Subsection §763.C.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§766	§35.920	59 FR 61767, 59 FR 65243	Added new qualifying certification for training in nuclear medicine, and amended to include human research subjects. Redesignated section as Subsection §763.D.
§767	§35.930	59 FR 61767, 59 FR 65243	Added new qualifying certification for training in nuclear medicine. Redesignated section as Subsection §763.E.
§770	§35.950	59 FR 61767, 59 FR 65243	Added new qualifying certification for training in nuclear medicine. Redesignated section as Subsection §763.H.
§771	§35.960	59 FR 61767, 59 FR 65243	Added new qualifying certification for training in nuclear medicine, and amended to include human research subjects. Redesignated section as Subsection §763.I.
§775	§35.972	59 FR 617675 9 FR 65243,	NRC changed their recentness of training requirement to 7 years, but ours can and will remain 5 years. Redesignated section as Subsection §763.O.
§777	§35.32	59 FR 61767, 59 FR 65243	Amended to include human research subjects.
§1012	§19.12	60 FR 36038	Replaced the phrase "All individuals working in or frequenting any portion of a restricted area" with " 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)," and rearranged the paragraphs to be more readable.
§1013	§20.2205	60 FR 36038	Replaced the term "individual" with the phrase, "identified occupationally exposed individual, or an identified member of the public," to the requirements for reporting incidents, planned special exposures, and exposures exceeding limits, in order to clarify requirements.

ERC SECTION	10 CFR SECTION	FED REG.	AMENDMENT ABSTRACT
§1307	§61.12	60 FR 15649, 60 FR 25983	Inserted requirement for electronic media.
§1333	§61.80	60 FR 15649, 60 FR 25983	Inserted requirement for electronic media, as well as requirements for further information on manifests.
§1701 , etc.	10 CFR 36	58 FR 7715	Added new chapter on irradiators, in accordance with SSRCR part Q (see addition to §326).

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 3. Licensing of Radioactive Material

' 325. General Requirements for the Issuance of Specific Licenses

* * *

[See Prior Text in A – D.6.d]

7. Each person licensed under this Chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with LAC 33:XV.331.B, licensees shall transfer all records described in this Paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated ~~by the division~~. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used ~~of relevant information are kept for other purposes, reference to these records and their locations may be used~~. Information the division considers important to decommissioning consists of the following:

* * *

[See Prior Text in D.7.a – d.iv]

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 23:1140 (September 1997), amended LR 24:2091 (November 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:** (2000).

§342. Records

A. If licensed activities are transferred or assigned in accordance with LAC 33:XV.331.B, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee, and the new licensee will be responsible for maintaining these records until the license is terminated:

1. records of disposal of licensed material made under LAC 33:XV.461, 462, 463, and 464; and

2. records required by LAC 33:XV.472.B.4.

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

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Environmental Assessment, Environmental Planning Division, LR 26:** (2000).

Title 33
ENVIRONMENTAL QUALITY
Part XV. Radiation Protection

Chapter 4. Standards for Protection Against Radiation

Subchapter I. Records

' 478. Records of Waste Disposal

* * *

[See Prior Text in A]

B. The licensee or registrant shall retain the records required by LAC 33:XV.478.A until the division terminates each pertinent license or registration requiring the record. Requirements for disposition of these records, prior to license termination, are located in LAC 33:XV.342.

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 by the Office of Environmental Assessment, Environmental Planning Division, LR 26:** (2000).

Termination or Transfer of Licensed Activities: Recordkeeping Requirements
(61 FR 24669; May 16, 1996) RATS ID 1996-3 Effective June 17, 1996

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§20.2108 (b)	Records of waste disposal		D	N/A	N/A		
§30.35 (g)	Financial assurance and recordkeeping for decommissioning		H&S	Paragraph revised to require the transfer of records pertaining to decommissioning to the new licensee.			
§40.36 (f)	Financial assurance and recordkeeping for decommissioning		H&S	Paragraph revised to require the transfer of records pertaining to decommissioning to the new licensee.			
§70.25 (g)	Financial assurance and recordkeeping for decommissioning		H&S	Paragraph revised to require the transfer of records pertaining to decommissioning to the new licensee.			
§30.36 (k)(4)	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas		H&S	Added to state that license will not be terminated until the NRC receives the records required by revised by Secs. 30.51, 40.61, and 70.51.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§40.42 (k)(4)	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas		H&S	Added to state that license will not be terminated until the NRC receives the records required by revised by Secs. 30.51, 40.61, and 70.51.			
§70.38 (k)(4)	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas		H&S	Added to state that license will not be terminated until the NRC receives the records required by revised by Secs. 30.51, 40.61, and 70.51.			
§30.51(d), (e),(f)	Records Material balance, inventory, and records requirements		H&S	Added to clarify that records pertaining to decommissioning, offsite releases, and certain records pertaining to waste disposal assignment, or to the NRC prior to license termination			
§40.61 (d),(e),(f)	Records Material balance, inventory, and records requirements		H&S	Added to clarify that records pertaining to decommissioning, offsite releases, and certain records pertaining to waste disposal assignment, or to the			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				NRC prior to license termination			
§70.51 (b)(6)	Records Material balance, inventory, and records requirements	478	C	Added to clarify that records pertaining to decommissioning, offsite releases, and certain records pertaining to waste disposal assignment, or to the NRC prior to license termination	No		
§70.51 (b)(7)	Records Material balance, inventory, and records requirements	478	C	Added to clarify that records pertaining to decommissioning, offsite releases, and certain records pertaining to waste disposal assignment, or to the NRC prior to license termination	No		
§61.30 (a)(3)	Transfer of license		H&S	Amended Paragraph: (a) * * *(3) That any funds for care and records required by §61.80(e) and (f) have been transferred to the disposal site owner;			
§61.31 (c)(3)	Termination of license		H&S	Amended Paragraph: (c) * * *(3) That the records required by §61.80(e) and (f) have been sent to the party responsible for institutional control of the disposal site and a copy has been sent to the			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				Commission immediately prior to license termination.			