Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 19. Nuclear Pharmacy

§1901. Cross References

A. For all regulations that apply to permitted nuclear pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1903. Definitions

A. As used in this chapter, the following terms shall have the meaning ascribed to them in this Section:

Nuclear Pharmacy – a board-approved facility limited to procuring, possessing, compounding, or dispensing radiopharmaceuticals or any interventional drug used in conjunction with nuclear medicine procedures. This definition shall not apply to hospital nuclear medicine departments and nuclear medicine clinics operating under the auspices of a licensed practitioner of medicine.

Radiation – any electromagnetic or ionizing radiation including gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles.

Radioactive Material – any solid, liquid, or gas that emits radiation spontaneously.

Radiopharmaceutical – a drug that is a radioactive material and includes any drug that is intended to be made radioactive, as defined by the appropriate federal agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1905. Nuclear Pharmacy Permit Requirements

A. A nuclear pharmacy permit shall be required to operate a nuclear pharmacy department. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

1. A nuclear pharmacy shall have a Louisiana Radioactive Material License.
2. Nuclear Pharmacist-in-Charge. A pharmacist-in-charge of a nuclear pharmacy operation shall be a qualified nuclear pharmacist, as defined in §1907, and shall be responsible for the entire nuclear pharmacy operation.
3. Structural Requirements. A nuclear pharmacy shall provide adequate space separate and apart from other areas commensurate with the scope of service and with the following space requirements:
    a. Dispensing Area. The radiopharmaceutical compounding or preparation area shall be separate and apart from other facility areas and shall be not less than 300 square feet, which may include storage and decay areas. The pharmacy area shall be sufficient to provide a work environment for the safe handling, compounding, and dispensing of radiopharmaceuticals. This area shall be separate and inaccessible to non-pharmacy personnel.
    b. Delivery and Receipt Area. An area designated for the delivery and receipt of materials requiring after-hours handling by non-pharmacy personnel. This area shall be separate from the dispensing area of the pharmacy.
    c. Storage Area. A storage area sufficient to maintain the scope and content of unused and returned material for decay and disposal commensurate with the compounding and dispensing requirements of the facility.
    d. Maintenance. A nuclear pharmacy shall be well maintained, clean, orderly, lighted, and properly ventilated.

e. Plumbing. A sink equipped with hot and cold running water shall be located within the nuclear pharmacy. A sink located in a pharmacy lavatory or restroom shall not be sufficient to satisfy this requirement.

4. Equipment. There shall be adequate equipment commensurate with the scope of services required and provided by the facility.
5. Supplies. There shall be adequate supplies commensurate with the compounding and dispensing needs of the facility, as well as any other services provided for by the facility, including appropriate shielding and safety devices and any other supplies necessary for the safe and legal transport of materials compounded or dispensed from the facility. There shall be appropriate supplies for the safe handling and disposal of used and unused material by employees and staff of the facility. The appropriateness of personal protective equipment shall be reviewed on an annual basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

§1907. Qualified Nuclear Pharmacist

A. A qualified nuclear pharmacist shall be a currently licensed pharmacist in the state of Louisiana who is listed on a Louisiana Radioactive Material License.

B. Continuing Education. Nuclear pharmacists shall obtain at least five hours of the total required hours of Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education on those applications and procedures specific to nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

§1909. Labeling

A. Immediate Container. The immediate container that comes into direct contact with the radiopharmaceutical shall be labeled with:
   1. the standard radiation symbol;
   2. the words “Caution – Radioactive Material”;
   3. the prescription control number;
   4. the name of the radionuclide; and
   5. the amount of radioactive material contained, in the appropriate unit of measure.

B. Outer Container. In addition to any labeling requirements of the board for non-radiopharmaceuticals, the outer container of a radiopharmaceutical to be dispensed shall also be labeled with:
   1. the standard radiation symbol;
   2. the words “Caution – Radioactive Material”;
   3. the name of the radionuclide;
   4. the chemical form;
   5. the amount of material contained, in the appropriate unit of measure;
   6. the liquid volume expressed in cubic centimeters or milliliters, where applicable; and
   7. the calibration time and date for the amount of radioactivity contained.

C. The labeling requirements in this Section shall not apply to transport containers.

D. Practitioner Administered Compounds Labeling. All practitioner administered compounds, as defined in Chapter 25 of these regulations, shall be dispensed or delivered in a suitable container with a label containing the following information:
   1. pharmacist’s name or initials;
   2. pharmacy’s name, address, and telephone number;
   3. preparation name;
   4. prescription number or pharmacy-assigned identification number;
   5. lot number;
   6. beyond-use date;
   7. strength and concentration;
   8. practitioner’s name; and
   9. special storage requirements, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

§1911. Quality Control & Quality Assurance

A. Quality control of radiopharmaceuticals is required on all radiopharmaceuticals compounded in a nuclear pharmacy. Appropriate quality assurance procedures shall be developed and followed for the procurement, compounding, and dispensing of all pharmaceuticals in a nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.