657—16.4(155A) General requirements for a pharmacy providing radiopharmaceutical services. A pharmacy providing radiopharmaceutical services shall obtain a limited use pharmacy license pursuant to rule 657—8.35(155A) prior to commencing provision of services in this state.

16.4(1) *Authorized nuclear pharmacist.* The pharmacist in charge shall be an authorized nuclear pharmacist and shall be responsible for, at a minimum, the requirements in rule 657—8.3(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of an authorized nuclear pharmacist. An authorized nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the drug compounding, dispensing, quality assurance, and office areas.

16.4(3) *Personnel appropriately trained.* The pharmacist in charge shall be responsible for ensuring that all pharmacy personnel have been appropriately and adequately trained for their assigned tasks.

16.4(4) *Pharmacy support persons.* A pharmacy support person shall register with the board pursuant to the registration requirements of 657—Chapter 5. Alternatively, a pharmacy support person may register with the board as a pharmacy technician pursuant to the registration and national certification requirements of 657—Chapter 3.

16.4(5) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board, the public health department, and the environmental protection commission.

16.4(6) *Compliance.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs. Nuclear pharmacies shall comply with all standards identified in United States Pharmacopeia General Chapter 825.

16.4(7) *Prescription and office use.* Radioactive drugs shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals to practitioners for office use.

16.4(8) *Outer-container label.* In addition to any of the board's labeling requirements for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

a. The standard radiation symbol;
b. The words "Caution — Radioactive Material";
c. The name of the radionuclide;
d. The chemical form;
e. The amount of radioactive material contained, in millicuries or microcuries;
f. If the radioactive drug is a liquid, the volume in cubic centimeters;
g. The requested calibration time for the amount of radioactivity contained.

16.4(9) *Immediate-container label.* The immediate container shall be labeled with:

a. The standard radiation symbol;
b. The words "Caution — Radioactive Material";
c. The name of the pharmacy; and
d. The prescription number.

16.4(10) *Radioactivity.* The amount of radioactivity for a radiopharmaceutical prepared by a nuclear pharmacy shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* When a nuclear pharmacy distributes to another entity radioactive drugs that are FDA-approved, commercially manufactured drug products, the pharmacy shall not process the radioactive drugs in any manner or violate the product packaging.

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