

WAC 246-903-020 Nuclear pharmacies. (1) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy and the state radiation control agency before approval of the license.

(3) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted professional standards.

(4) The board recognizes that the preparation of nuclear pharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(5) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies.

(6) For nuclear pharmacies handling radiopharmaceuticals exclusively, the state board of pharmacy may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(7) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(8) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(9) In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (a) Standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the radiopharmaceutical; (d) the amount of radioactive material contained, in millicuries or microcuries; (e) if a liquid, the volume in milliliters; (f) the requested calibration time for the amount of radioactivity contained; (g) expiration data, if applicable; and (h) specific concentration of radioactivity.

(10) The immediate container shall be labeled with: (a) The standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the nuclear pharmacy; (d) the prescription number; (e) the name of the radiopharmaceutical; (f) the date; and (g) the amount of radioactive material contained in millicuries or microcuries.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency.

(14) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license.

[Statutory Authority: RCW 18.64.005. WSR 93-04-016 (Order 329B), § 246-903-020, filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-030, filed 2/1/79.]