

WAC 246-945-490 Nuclear pharmacies. (1) The commission shall issue a permit to operate a nuclear pharmacy providing radiopharmaceutical services to a qualified nuclear pharmacist. The qualified nuclear pharmacist shall:

(a) Supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals.

(b) Be responsible for all operations of the licensed area.

(c) Designate one or more qualified health care professionals licensed under the chapters specified in RCW 18.130.040, to have access to the licensed area in emergency situations and in the nuclear pharmacist's absence. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) A nuclear pharmacy shall have adequate space that is appropriate with the scope of services provided, including meeting the following requirements:

(a) The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel;

(b) A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the commission; and

(c) Detailed floor plans shall be submitted to the commission and the state radiation control agency before approval of the pharmacy license.

(3) A nuclear pharmacy shall prepare, compound, and dispense radiopharmaceuticals in accordance with USP <825>.

(4) The preparation of nuclear pharmaceuticals requires the compounding skills of the nuclear pharmacist and shall be done to assure that the final drug product meets USP <825>.

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

(6) For a nuclear pharmacy handling radiopharmaceuticals exclusively, the commission 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. In absence of a prescription for an individual identified patient, the statement "Office Use Only" should be applied.

(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 labeling requirements of WAC 246-945-015 through 246-945-017 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) Radionuclide and chemical form (generic name);

(d) Activity dispensed with units (millicuries or microcuries) at calibration date and time;

(e) If a liquid, the volume in milliliters;

- (f) Calibration date and time for the dose;
 - (g) BUD and special storage and handling instructions for nonimmediate use;
 - (h) Specific concentration of radioactivity; and
 - (i) The patient name/identifier, and number of dosage units dispensed, for all therapeutic and blood-products.
- (10) The immediate container of the radiopharmaceutical to be dispensed 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) Radionuclide and chemical form (generic name)";
 - (f) The date;
 - (g) Activity dispensed with units (millicuries or microcuries) at calibration date and time; and
 - (h) The patient name/identifier for all therapeutic and blood-products.
- (11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.
- (12) A nuclear pharmacy 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 readily available the current applicable state laws and regulations of the commission and state radiation control agency.
- (14) The nuclear pharmacy shall maintain, and submit to the commission and state radiation control agency, a library commensurate with the level of radiopharmaceutical service to be provided before approval of the license.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-490, filed 6/1/20, effective 7/1/20.]