WAC 246-235-100 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under chapter 246-240 WAC. (1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to chapter 246-240 WAC will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 246-235-020;

(b) The applicant submits evidence of at least one of the following:

(i) Is registered with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. Part 207, Subpart B;

(ii) Is registered or licensed with the pharmacy quality assurance commission as a drug manufacturer;

(iii) Is licensed as a pharmacy by the pharmacy quality assurance commission;

(iv) Is operating as a nuclear pharmacy within a federal medical institution; or

(v) Is a positron emission tomography drug production facility registered with the Washington state pharmacy quality assurance commission.

(c) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(d) The applicant commits to the following labeling requirements:

(i) A 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 must include the radiation symbol, 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 must include the radiation symbol, 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.

(2) A licensee who is licensed as a pharmacy by the Washington state pharmacy quality assurance commission, or who is operating as a nuclear pharmacy within a federal medical institution:

(a) May prepare radioactive drugs for medical use, as defined in WAC 246-240-010, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in (b) and (d) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist as specified in WAC 246-240-057.

(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 WAC 246-240-010;

(ii) This individual meets the requirements of WAC 246-240-081 and 246-240-075(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 (d) of this subsection.

(c) The actions authorized in (a) and (b) of this subsection are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist, as defined in WAC 246-240-010, as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(ii) The individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at any other pharmacies before August 8, 2009.

(e) Must provide to the department:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in WAC 246-240-075(1); or

(ii) The NRC or agreement state license; or

(iii) The NRC master materials licensee permit; or

(iv) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009; and

(vi) A copy of the Washington state pharmacy license or registration, no later than 30 days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist under (b)(i) or (iii) of this subsection.

(3) A licensee must possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee must have procedures for use of the instrumentation. The licensee must 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 must:

(a) Perform tests on each instrument before initial use, periodically, and following repair, 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) A licensee must satisfy the labeling requirements in subsection (1)(d) of this section.

(5) Nothing in this section relieves the licensee from complying with applicable United States Food and Drug Administration requirements, other federal requirements, and state requirements governing radioactive drugs.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-100, filed 9/20/22, effective 10/21/22. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-100, filed 2/23/15, effective

3/26/15; WSR 13-24-025, § 246-235-100, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-100, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 07-14-131, § 246-235-100, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-235-100, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-235-100, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-100, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-100, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-22-110, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-110, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-076.]