

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

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

(b) The applicant submits evidence that the applicant is:

(i) Registered or licensed with the Food and Drug Administration (FDA) as a drug manufacturer, preparer, propagator, compounder or processor of a drug under 21 C.F.R. 207.20(a); or

(ii) Licensed as a nuclear pharmacy by the Pharmacy Quality Assurance Commission;

(iii) Registered or licensed as a radiopharmaceutical production facility or nuclear pharmacy with the NRC or a state agency;

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

(v) A positron emission tomography drug production facility registered with a state agency.

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

(d) The applicant satisfies the following labeling requirements:

(i) Those specified by the Pharmacy Quality Assurance Commission in WAC 246-903-020 for both commercial and noncommercial distribution;

(ii) 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 one hundred days, the time may be omitted;

(iii) 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 allows the syringe, vial, or other container to be correlated with the information on the transport radiation shield label; and

(iv) For a drug manufacturer, the labels required by this subsection are in addition to the labeling required by the Food and Drug Administration (FDA) and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(2) A medical facility or an educational institution, may produce positron emission tomography or other approved accelerator-produced radioactive drugs, for noncommercial transfer to licensees within their consortium, as defined in WAC 246-220-010 and 246-235-010, if they have a valid Washington radioactive materials license and are authorized for medical use under chapter 246-240 WAC or an equivalent agreement state or NRC license; and

(a) Request authorization to produce accelerator-produced radionuclides at a radionuclide production facility within their consortium

to prepare approved radioactive drugs for use only by licensees within that consortium. The applicant must have a current state radioactive materials license or evidence of an existing license issued by an agreement state.

(b) The applicant must be qualified to produce radioactive drugs for medical use by meeting the criteria in subsections (1) and (3) of this section.

(c) Identification of individual(s) authorized to prepare radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in subsection (3) of this section.

(d) Labeling information identified in subsection (1)(d) of this section is applied to any radiopharmaceuticals or radioactive materials to be noncommercially transferred to members of its consortium.

(3) A nuclear pharmacy licensee:

(a) May prepare radiopharmaceuticals for medical use provided the radiopharmaceutical is prepared by or under the supervision of an authorized nuclear pharmacist.

(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 Pharmacy Quality Assurance Commission requirements in WAC 246-903-030, Nuclear pharmacists, and the requirements of WAC 246-240-081 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 an authorized nuclear pharmacist if:

(i) The individual was identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the department, the NRC, or an agreement state; or

(ii) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at any other pharmacies as of December 1, 2008.

(e) Shall provide to the department a copy of each individual's letter of notification from the Pharmacy Quality Assurance Commission recognizing the individual as a nuclear pharmacist, within thirty days of the date the licensee allows the individual to work as an authorized nuclear pharmacist under (b), (c) or (d) of this subsection.

(4) A manufacturer or nuclear pharmacy licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals, prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests on each instrument before initial use, periodically, and following repair, for accuracy, linearity, and geometry de-

pendence, 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.

(5) A licensee preparing radiopharmaceuticals from generators; (e.g., molybdenum-99/technetium-99m or rubidium-82 from strontium-82/rubidium-82) shall test generator eluates for breakthrough or contamination of the parent nuclide, in accordance with WAC 246-240-160. The licensee shall record the results of each test and retain each record for three years after the record is made.

(6) Nothing in this section relieves the licensee from complying with applicable FDA, federal, and state requirements governing radiopharmaceuticals.

[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.]