

WAC 246-232-050 Terms and conditions of licenses. (1) Each license issued pursuant to the rules in chapters 246-220 through 246-254 WAC is subject to all the provisions of chapter 70A.388 RCW, and to all applicable rules and orders of the department.

(2)(a) No license issued or granted under chapters 246-220 through 246-254 WAC nor any right under a license may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the department finds, after securing full information, that the transfer is in accordance with the provisions of chapter 70A.388 RCW, and gives its consent in writing.

(b) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by WAC 246-235-075.

(3) Each person licensed by the department pursuant to chapters 246-220 through 246-254 WAC shall confine use and possession of the radioactive material to the locations and purposes authorized by the license. Except as otherwise provided in the license, a license issued pursuant to the rules in chapters 246-220 through 246-254 WAC carries with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of chapter 246-231 WAC.

(4) Approval of licensee's procedures by the department does not release the licensee from responsibility if adherence to these procedures results in undue exposure to individuals or loss of control of radioactive material.

(5) The department may incorporate, in any license issued pursuant to the rules in chapters 246-220 through 246-254 WAC, at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:

(a) Protect health or to minimize danger to life or property;

(b) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of chapters 70A.388 RCW and 246-220 through 246-254 WAC.

(6) Licensees required to submit emergency plans by WAC 246-235-077 must follow the emergency plan approved by the department. The licensee may change the approved emergency plan without department approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the department and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the department.

(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with WAC 246-240-160. The licensee must record the results of each test and retain each record for three years after the record is made. The licensee must report the results of any test that exceeds the permissible concentration listed in

WAC 246-240-160(1) at the time of generator elution, in accordance with WAC 246-240-660.

(8) Each specific licensee must notify the department of health, office of radiation protection, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(a) The licensee;

(b) An entity (as the term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as the term is defined in 11 U.S.C. 101(2)) of the licensee.

(9) The specific licensee's bankruptcy notification must include:

(a) The bankruptcy court in which the petition for bankruptcy was filed;

(b) The date of the filing of the petition;

(c) A complete and detailed inventory of all radioactive material possessed under the license including nuclide, form, activity and planned disposition;

(d) An estimation of the type and quantities of radioactive material the licensee plans to continue to receive or use on a routine basis;

(e) A description of security and storage for the radioactive material currently possessed;

(f) A plan for radioactive waste disposal, the estimated completion date(s), and the cost;

(g) An evaluation of facility and equipment contamination, estimate of clean-up costs, and a decontamination plan which includes a thorough description of how the cleanup will be funded and how it will be accomplished;

(h) An organizational chart specifying sole owners, partnerships, or officers in the corporation who have legal and fiscal responsibilities for the licensee;

(i) A description of any other changes affecting the terms and conditions of the radioactive materials license.

(10) Each specific licensee must notify the department within five working days if any items in subsection (9) of this section change during bankruptcy proceedings.

(11) The department will consider clean-up costs as part of the licensee's administrative costs if decontamination is necessary to comply with chapters 246-220 through 246-254 WAC.

(12) Each general licensee required to register by WAC 246-233-020 (3)(k) must notify the department of health, radiation protection, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(a) The licensee;

(b) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(13) The general licensee's bankruptcy notification must include:

(a) The bankruptcy court in which the petition for bankruptcy was filed; and

(b) The date of the filing of the petition.

(14) Security requirements for portable gauges. Each portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(15)(a) Authorization under WAC 246-235-010 to produce positron emission tomography radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable United States Food and Drug Administration, other federal, and state requirements governing radioactive drugs.

(b) Each licensee authorized under WAC 246-235-010 to produce positron emission tomography radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in WAC 246-235-100 for each positron emission tomography radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a positron emission tomography radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the positron emission tomography radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in WAC 246-235-100.

(c) A licensee that is a pharmacy authorized under WAC 246-235-010 to produce positron emission tomography radioactive drugs for noncommercial transfer to medical use licensees in its consortium must require that any individual that prepares positron emission tomography radioactive drugs must be:

(i) An authorized nuclear pharmacist that meets the requirements in WAC 246-235-100; or

(ii) An individual under the supervision of an authorized nuclear pharmacist as specified in WAC 246-240-057.

(d) A pharmacy, authorized under WAC 246-235-010 to produce positron emission tomography radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, must meet the requirements of WAC 246-235-100.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-232-050, filed 9/20/22, effective 10/21/22. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-050, filed 11/22/13, effective 12/23/13; WSR 04-04-055, § 246-232-050, filed 1/30/04, effective 3/1/04. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 92-06-008 (Order 245), § 246-232-050, filed 2/21/92, effective 3/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-050, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-19-300, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-19-300, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-19-300, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-19-300, filed 11/30/79, effective 1/1/80.]