

WSR 22-19-084

PERMANENT RULES

DEPARTMENT OF HEALTH

[Filed September 20, 2022, 2:08 p.m., effective October 21, 2022]

Effective Date of Rule: Thirty-one days after filing.

Purpose: The department of health (department) adopted amendments to revise chapter 246-232 WAC, Radioactive material—Licensing applicability; chapter 246-235 WAC, Radioactive materials—Specific licenses; and chapter 246-240 WAC, Radiation protection—Medical use of radioactive material to be consistent with the United States Nuclear Regulatory Commission's (NRC) rule changes identified by the Regulation Amendments Tracking System (RATS) 2018-1 document and to make nonsubstantive editorial changes. This rule making was required to comply with RCW 70A.388.040 State radiation control agency, and 70A.388.110 Federal-state agreements. As stated under this formal state agreement between the governor and NRC, the department is required to remain compatible with NRC rules. This is done through rule amendments to make state rules consistent with, and at-least-as-stringent-as, NRC's rules.

Citation of Rules Affected by this Order: New WAC 246-232-004, 246-232-005 and 246-240-660; and amending WAC 246-232-006, 246-232-008, 246-232-009, 246-232-014, 246-232-040, 246-232-050, 246-232-060, 246-232-080, 246-232-130, 246-232-140, 246-235-010, 246-235-020, 246-235-075, 246-235-077, 246-235-080, 246-235-086, 246-235-090, 246-235-091, 246-235-093, 246-235-100, 246-235-103, 246-235-109, 246-240-010, 246-240-016, 246-240-019, 246-240-022, 246-240-025, 246-240-028, 246-240-051, 246-240-060, 246-240-063, 246-240-069, 246-240-072, 246-240-075, 246-240-078, 246-240-104, 246-240-107, 246-240-110, 246-240-113, 246-240-119, 246-240-122, 246-240-128, 246-240-154, 246-240-160, 246-240-163, 246-240-201, 246-240-210, 246-240-213, 246-240-216, 246-240-219, 246-240-251, 246-240-272, 246-240-278, 246-240-281, 246-240-301, 246-240-304, 246-240-351, 246-240-354, 246-240-357, 246-240-360, 246-240-363, 246-240-366, 246-240-369, 246-240-372, 246-240-375, 246-240-378, 246-240-381, 246-240-384, 246-240-390, 246-240-393, 246-240-399, 246-240-551, 246-240-578, 246-240-590, 246-240-605, 246-240-614, 246-240-632, 246-240-651 and 246-240-654.

Statutory Authority for Adoption: RCW 70A.388.040.

Other Authority: RCW 70A.388.110.

Adopted under notice filed as WSR 22-15-036 on July 14, 2022.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 3, Amended 79, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 3, Amended 79, Repealed 0.

Date Adopted: September 20, 2022.

Lauren Jenks

OTS-3837.3

GENERAL PROVISIONSNEW SECTION

WAC 246-232-004 Completeness and accuracy of information. (1) Information provided to the department by an applicant for a license or by a licensee or information required by statute or by the department's rules, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(2) Each applicant or licensee must notify the department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety. An applicant or licensee violates this subsection only if the applicant or licensee fails to notify the department of information that the applicant or licensee has identified as having a significant implication for public health and safety. Notification must be provided to the department within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the department by other reporting or updating requirements.

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NEW SECTION

WAC 246-232-005 Deliberate misconduct. (1) Any licensee; certificate of registration holder; applicant for a license or certificate of registration; employee of a licensee or certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration; who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, or applicant's activities in chapters 246-220 through 246-254 WAC, may not:

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the department; or

(b) Deliberately submit to the department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the department.

(2) A person who violates subsection (1)(a) or (b) of this section may be subject to enforcement action under chapter 70A.388 RCW.

(3) For the purposes of subsection (1)(a) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license issued by the department; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

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EXEMPTIONS

AMENDATORY SECTION (Amending WSR 17-01-034, filed 12/12/16, effective 1/12/17)

WAC 246-232-006 Exemption of certain source material. (1) A person is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent that the person receives, possesses, uses, transfers, or delivers, source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(2) A person is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent that the person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material, provided such person shall not refine or process such ore unless authorized to do so in a specific license.

(3) A person is exempt from the requirements for a license and from this chapter and chapters 246-221, 246-246, 246-222, 246-233, and 246-235 WAC to the extent that the person receives, possesses, uses or transfers:

(a) Any quantities of thorium contained in:

(i) Incandescent gas mantles;

(ii) Vacuum tubes;

(iii) Welding rods;

(iv) Electric lamps for illuminating purposes if each lamp contains (~~fifty~~) 50 milligrams or less of thorium;

(v) Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting if each lamp contains two grams or less of thorium;

(vi) Rare earth metals and compounds, mixtures, and products containing 0.25 percent or less by weight thorium, uranium, or any combination of these; or

(vii) Personnel neutron dosimeters if each dosimeter contains 1.85 gigabecquerels (50 milligrams) or less of thorium.

(b) Source material contained in the following products:

(i) Glazed ceramic tableware manufactured before August 27, 2013, if the glaze contains (~~twenty~~) 20 percent or less by weight source material;

(ii) Piezoelectric ceramic containing two percent or less by weight source material; and

(iii) Glassware containing not more than two percent by weight source material or, for glassware manufactured before August 27, 2013, (~~ten~~) 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction.

(c) Photographic film, negatives and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys if the thorium content of the alloy is four percent or less by weight. The exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(e) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than (~~ten~~) 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, (~~thirty~~) 30 percent by weight of thorium. The exemption contained in this subparagraph shall not be deemed to authorize either:

(i) The shaping, grinding or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without alteration of the lens or mirror; or

(ii) The receipt, possession, use or transfer of thorium or uranium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(f) Uranium contained in detector heads for use in fire detection units if each detector head contains 185 becquerels (0.005 microcuries) or less of uranium; or

(g) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy if:

(i) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(ii) The thorium content in the nickel-thoria alloy is four percent or less by weight.

(4) The exemptions in subsection (3) of this section do not authorize the manufacture of any of the products described.

(5) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this section, or equivalent regulations of an agreement state or the NRC, unless authorized by a license issued under 10 C.F.R. 40.52 to initially transfer such products for sale or distribution.

(a) Persons initially distributing source material in products covered by the exemptions in this section before August 27, 2013, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued un-

til NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(b) Persons authorized by an agreement state to manufacture, process, or produce these materials or products containing source material, and persons who import finished products or parts for sale or distribution must be authorized by a license issued under 10 C.F.R. 40.52 for distribution only and are exempt from the requirements of chapters 246-221 and 246-222 WAC, and WAC 246-235-020 (1) and (2).

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-232-006, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-232-006, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-006, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-232-006, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 01-02-068, § 246-232-006, filed 12/29/00, effective 1/29/01.]

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-232-008 Exemption of certain timepieces, hands or dials.

No person may introduce radioactive material into a product or material, knowing or having reason to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC, Washington, D.C. 20555. A person is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent that the person receives, possesses, uses, transfers, owns or acquires, and does not apply radioactive material to, or incorporate radioactive material into, the following timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation(~~(*)~~):

(*Note: No person may introduce radioactive material into a product or material, knowing or having reason to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC, Washington, D.C. 20555.)

(1) (a) (~~(925)~~) Nine hundred twenty-five megabecquerels (25 millicuries) of tritium per timepiece;

(b) (~~(185)~~) One hundred eighty-five megabecquerels (~~((5))~~) five millicuries) of tritium per hand;

(c) (~~(555)~~) Five hundred fifty-five megabecquerels (15 millicuries) of tritium per dial (bezels when used shall be considered as part of the dial);

(d) 3.7 megabecquerels (100 microcuries) of promethium-147 per watch or 7.4 megabecquerels (200 microcuries) of promethium-147 per any other timepiece;

(e) (~~(740)~~) Seven hundred forty kilobecquerels (20 microcuries) of promethium-147 per watch hand or 1.48 megabecquerels (40 microcuries) of promethium-147 per other timepiece hand;

(f) 2.22 megabecquerels (60 microcuries) of promethium-147 per watch dial or 4.44 megabecquerels (120 microcuries) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(2) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a) For wrist watches, ((±)) one microgray (0.1 millirad) per hour at 10 centimeters from any surface;

(b) For pocket watches, ((±)) one microgray (0.1 millirad) per hour at ((±)) one centimeter from any surface;

(c) For any other timepiece, ((2)) two micrograys (0.2 millirad) per hour at 10 centimeters from any surface.

(3) ((37)) Thirty-seven kilobecquerels ((±)) one microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-008, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-232-008, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 01-02-068, § 246-232-008, filed 12/29/00, effective 1/29/01.]

AMENDATORY SECTION (Amending WSR 17-01-034, filed 12/12/16, effective 1/12/17)

WAC 246-232-009 Exemption of certain items containing radioactive material. No person may introduce radioactive material into a product or material, knowing or having reason to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC, Washington, D.C. 20555. A person is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent the person receives, possesses, uses, transfers, owns or acquires, and does not apply radioactive material to, or incorporate radioactive material into, the following products: ((*))

(*Note: No person may introduce radioactive material into a product or material, knowing or having reason to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC, Washington, D.C. 20555.)

(1) Static elimination devices which contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 microcuries) of Po-210 per device.

(2)(a) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 microcuries) of Po-210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen-3 (tritium) per device.

(b) Such devices authorized before October 23, 2012, for use under the general license then provided in this section and equivalent regulations of an agreement state or the NRC, and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the department, an agreement state, or the NRC.

(3) Balances of precision containing not more than 37 megabecquerels ((±)) one millicurie) of tritium per balance or 18.5 megabecquerels (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007.

(4) Marine compasses containing not more than 27.8 gigabecquerels (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 gigabecquerels (250 millicuries) of tritium gas manufactured before December 17, 2007.

(5) Ionization chamber smoke detectors containing not more than 37 kilobecquerels ((±) one microcurie) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(6) For purposes of this subsection, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents. Electron tubes(*) provided that each tube contains no more than one of the following specified quantities of radioactive material and the levels of radiation from each electron tube do not exceed 10 micrograys ((±) one millirad) per hour at ((±) one centimeter from any surface when measured through ((7) seven milligrams per square centimeter of absorber:

(a) 5.55 gigabecquerels (150 millicuries) of tritium per microwave receiver protector tube or 370 megabecquerels (10 millicuries) of tritium per any other electron tube;

(b) ((37)) Thirty-seven kilobecquerels ((±) one microcurie) of cobalt-60;

(c) ((185)) One hundred eighty-five kilobecquerels ((5)) five microcuries) of nickel-63;

(d) 1.11 megabecquerels (30 microcuries) of krypton-85;

(e) ((185)) One hundred eighty-five kilobecquerels ((5)) five microcuries) of cesium-137;

(f) 1.11 megabecquerels (30 microcuries) of promethium-147.

(*)Note: For purposes of this subsection, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.))

(7) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(a) Each source contains not more than one exempt quantity set forth in WAC 246-232-120, Schedule B, exempt quantities of radioactive materials; and

(b) Each instrument contains no more than 10 exempt quantities. For purposes of this subsection, an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in WAC 246-232-120, Schedule B, exempt quantities of radioactive materials, provided that the sum of such fractions must not exceed unity.

(c) For purposes of this subsection, 1.85 kilobecquerels (0.05 microcurie) of americium-241 is considered an exempt quantity.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-232-009, filed 12/12/16, effective 1/12/17. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-009, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-232-009, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 01-02-068, § 246-232-009, filed 12/29/00, effective 1/29/01.]

AMENDATORY SECTION (Amending WSR 16-13-054, filed 6/10/16, effective 7/11/16)

WAC 246-232-014 Exemption of C-14 urea diagnostic capsules for human use. (1) Except as provided in subsections (2) and (3) of this section, a person is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC if the person receives, possesses, uses, transfers, owns, or acquires, and does not apply radioactive material to, or incorporate radioactive material into, capsules containing 37 kilobecquerels ((~~4~~) one microcurie) of carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in-vivo" diagnostic use for humans.

(2) A person who desires to use the capsules for research involving human subjects must apply for and receive a specific license under chapters 246-240 and 246-235 WAC.

(3) A person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution these capsules must do so in accordance with a specific license issued by the NRC, Washington, D.C. 20555.

(4) Nothing in this section relieves persons from complying with applicable United States Food and Drug Administration, federal, and state requirements governing receipt, administration, and use of drugs.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-232-014, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-014, filed 11/22/13, effective 12/23/13; WSR 06-05-019, § 246-232-014, filed 2/6/06, effective 3/9/06; WSR 01-02-068, § 246-232-014, filed 12/29/00, effective 1/29/01.]

LICENSES

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-232-040 Reciprocal recognition of licenses. Before radioactive material can be used at any temporary job site, the jurisdictional status of the job site must be determined. Authorization for use of radioactive material at job sites under exclusive federal jurisdiction must be obtained from the appropriate regional office of the NRC, Washington, D.C. 20555. Before radioactive materials can be used as a temporary job site in another state, authorization must be obtained from that state if it is an agreement state, or from the NRC if it is a nonagreement state.

(1) A person authorized by a license issued by the NRC or an agreement state, may obtain authorization from the department to work in Washington state provided:

(a) The out-of-state license is issued by the NRC or agreement state with jurisdiction where the licensee maintains an office for directing the licensed work and for retaining radiation safety records;

(b) The out-of-state licensee must not possess or use radioactive materials or conduct authorized work in Washington state for more than (~~one hundred eighty~~) 180 days in that (~~twelve month~~) 12-month period which starts the date approval is granted, and the appropriate fee is received by the department, as required in chapter 246-254 WAC;

(c) The out-of-state licensing document authorizes the work conducted;

(d) The licensed work is not conducted in an area under exclusive federal jurisdiction;

(e) The appropriate fee is currently paid, as required in chapter 246-254 WAC. Licensees send fees to Washington State Department of Health, Revenue Accounting, P.O. Box 1099, Olympia, Washington 98504-1099;

(f) The out-of-state licensee notifies the department in writing at least three days before each entry into Washington state to conduct licensed work.

(i) The written notification must be sent to the Radioactive Materials Section, Department of Health, P.O. Box 47827, Olympia, Washington 98504-7827. Fax, email, or other notifications may be approved by the department.

(ii) The written notification must include use and storage location(s), start and end dates of licensed work, and type of proposed possession and use in Washington state, and must include licensing documents authorizing the licensed work.

(iii) If an unexpected need or emergency means the three-day notice is impossible or would impose an undue hardship on the out-of-state licensee, the out-of-state licensee may telephone the department (360-236-3221), for permission to proceed immediately.

(iv) The department may waive the requirement for filing additional written notifications during the remainder of the (~~twelve~~) 12 months following the receipt of the initial notification.

(g) The out-of-state licensee must:

(i) Comply with all terms and conditions of the licensing document issued by the licensing authority except such terms or conditions contrary to the requirements or rules of the department or this section;

(ii) Comply with all applicable rules, terms and conditions of the department; and

(iii) Promptly provide other information the department may request.

(h) The out-of-state licensee must request approval for changes in work locations, radioactive material, or work conducted if different from the most recent information provided to the department.

(i) The out-of-state licensee may not transfer or dispose of radioactive material except by transfer to a person specifically licensed by the department or by the NRC or an agreement state to receive such material.

(j) The out-of-state specific licensee may possess or use radioactive material or conduct authorized work in offshore waters for more than (~~one hundred eighty~~) 180 days in any calendar year, if the specific license issued by an agreement state or the NRC authorizes the specific licensee to possess or use radioactive material or conduct authorized work in offshore waters for an unlimited period of time.

(2) A person who holds a specific license issued by the NRC or an agreement state authorizing the holder to manufacture, install, or service a device described in WAC 246-233-020 within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install and service such device in this state in areas not under exclusive federal jurisdiction provided:

(a) Such person must file a report with the department within ~~((thirty))~~ 30 days after the end of each calendar quarter in which any device is transferred to or from, or installed in this state. Each report must identify each general licensee to or from whom such device is transferred by name and address, the device manufacturer (or initial transferor), model number and serial number, and the quantity and type of radioactive material contained in the device;

(b) The device has been, and is, manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to a person by the NRC or an agreement state;

(c) Such person must ensure that any labels required to be affixed to the device under rules of the authority which licensed the manufacture of the device bear a statement that removal of the label is prohibited; and

(d) The specific licensee must provide each general licensee to and from whom such device is transferred, or on whose premises such device is installed, a copy of the general license in WAC 246-233-020.

(3) The department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary to prevent undue hazard to public health and safety, or to the environment, or to property.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-040, filed 11/22/13, effective 12/23/13; WSR 04-04-055, § 246-232-040, filed 1/30/04, effective 3/1/04; WSR 01-02-068, § 246-232-040, filed 12/29/00, effective 1/29/01; WSR 99-15-105, § 246-232-040, filed 7/21/99, effective 8/21/99; WSR 98-13-037, § 246-232-040, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-232-040, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-19-250, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-19-250, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-19-250, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-19-250, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-210.]

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-232-050 Terms and conditions of licenses. (1) Each license issued pursuant to ~~((this part shall be))~~ the rules in chapters 246-220 through 246-254 WAC is subject to all the provisions of ~~((the act, as now or hereafter in effect))~~ chapter 70A.388 RCW, and to all applicable rules ~~((, regulations,))~~ and orders of the department.

(2) (a) No license issued or granted under chapters ((246-232, 246-233, or 246-235 WAC and no right to possess or use radioactive material granted by any license issued pursuant to chapters 246-233 and 246-235 WAC shall)) 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 ((shall)) finds, after securing full information, ((find)) that the transfer is in accordance with the provisions of ((the act)) 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 ((246-233 and 246-235)) 246-220 through 246-254 WAC shall confine use and possession of the radioactive material ((licensed)) 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.

~~((6))~~ (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.

~~((7))~~ (10) Each specific licensee must notify the department within five working days if any items in subsection ~~((6))~~ (9) of this section change during bankruptcy proceedings.

~~((8))~~ (11) The department will consider clean-up costs as part of the licensee's administrative costs if decontamination is necessary to comply with ~~((these regulations))~~ chapters 246-220 through 246-254 WAC.

~~((9))~~ (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.

~~((10))~~ (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.

~~((11) For the purposes of this section, "affiliate" means:~~

~~(a) A person as defined in WAC 246-220-010 that directly or indirectly owns, controls, or holds with power to vote, twenty percent or more of the outstanding voting securities of the licensee (unless that person holds such securities (i) in a fiduciary or agency capacity without sole discretionary power to vote such securities, or (ii) solely to secure a debt, if such person has not in fact exercised such power to vote);~~

~~(b) A corporation, twenty percent or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by the licensee;~~

~~(c) A person whose business is operated under a lease or operating agreement by a licensee, or person substantially all of whose property is operated under an operating agreement with the licensee; or~~

~~(d) A person that operates the business or substantially all of the property of the licensee under a lease or operating agreement.)~~

(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 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.]

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-232-060 Termination of licenses and decommissioning of sites and separate buildings or outdoor areas. (1) Each specific licensee shall immediately notify the department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license and request termination of the license. This notification and request for termination of the license must include the reports and information specified in subsection (3)(c) and (d) of this section. The licensee is subject to the provisions of subsections (3) and (4) of this section, as applicable.

(2) No less than (~~thirty~~) 30 days before the expiration date specified in a specific license, the licensee shall either:

(a) Submit an application for license renewal under WAC 246-235-050; or

(b) Notify the department in writing if the licensee decides not to renew the license.

(3) If a specific licensee does not submit an application for license renewal under WAC 246-235-050, the licensee shall on or before the expiration date specified in the license:

(a) Terminate use of radioactive material;

(b) Properly dispose of radioactive material;

(c) Submit a completed departmental form "Certificate of disposition of radioactive material" or equivalent; and

(d) Submit a radiation survey report to confirm the absence of radioactive materials or establish the levels of radioactive contamination, unless the department determines a radiation survey report is not necessary.

(i) If no radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted under this paragraph and subsection (3)(c) and (d) of this section is adequate, the department will notify the licensee in writing that the license is terminated.

(ii) If detectable levels of radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as con-

tamination until the licensee meets the criteria established in chapter 246-246 WAC and the department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of subsection (4) of this section. In addition to the information submitted under subsection (3)(c) and (d) of this section, the licensee shall submit a plan for decontamination, if necessary.

(4) Each specific licensee who possesses residual radioactive material under subsection (3)(d)(ii) of this section, following the expiration of the license, shall:

(a) Be limited to actions, involving radioactive material related to decontamination and preparation for release in accordance with chapter 246-246 WAC; and

(b) Continue to control entry to restricted areas until:

(i) Such areas are suitable for release in accordance with chapter 246-246 WAC;

(ii) Contaminated equipment complies with guidance contained in WAC 246-232-140, Schedule D; and

(iii) The department notifies the licensee in writing that the license is terminated.

(5) Each general licensee licensed under the provisions of WAC 246-233-040, shall immediately notify the department in writing when the licensee decides to discontinue all activities involving radioactive materials authorized under the general license. Such notification shall include a description of how the generally licensed material was disposed and the results of facility surveys, if applicable, to confirm the absence of radioactive materials.

(6) Within (~~sixty~~) 60 days of the occurrence of any of the following, each specific licensee shall provide notification to the department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the site, building, or outdoor area is suitable for release in accordance with chapter 246-246 WAC, or submit within (~~twelve~~) 12 months of notification a decommissioning plan, if required by subsection (10)(a) of this section, and begin decommissioning upon approval of that plan if:

(a) The license has expired or has been revoked by the department; or

(b) The licensee has decided to permanently cease principal activities, as defined in this section, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the site, building, or outdoor area is unsuitable for release in accordance with chapter 246-246 WAC; or

(c) No principal activities under the license have been conducted for a period of (~~twenty-four~~) 24 months; or

(d) No principal activities have been conducted for a period of (~~twenty-four~~) 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with chapter 246-246 WAC.

(7) As used in this section, principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

(8) Coincident with the notification required by subsection (6) of this section, the licensee shall maintain in effect all decommis-

sioning financial assurances established by the licensee pursuant to WAC 246-235-075 or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subsection (10)(d)(v) of this section. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the department.

(9) The department may grant a request to extend the time periods established in subsection (6) of this section if the department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than (~~thirty~~) 30 days before notification pursuant to subsection (6) of this section. The schedule for decommissioning set forth in subsection (6) of this section may not commence until the department has made a determination on the request.

(10)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(b) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to subsection (6) of this section if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(c) Procedures such as those listed in (a) of this subsection with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey;

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning;

(vi) A description of the physical security plan and material control and accounting plan provisions in place during decommissioning;

(vii) For decommissioning plans calling for completion of decommissioning later than (~~twenty-four~~) 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in subsection (12) of this section.

(e) The proposed decommissioning plan will be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(11)(a) Except as provided in subsection (12) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than (~~twenty-four~~) 24 months following the initiation of decommissioning.

(b) Except as provided in subsection (12) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than (~~twenty-four~~) 24 months following the initiation of decommissioning.

(12) The department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted by consideration of the following:

(a) Whether it is technically feasible to complete decommissioning within the allotted (~~twenty-four month~~) 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted (~~twenty-four month~~) 24-month period;

(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(e) Other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(13) As the final step in decommissioning, the licensee shall:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed certificate of disposition of radioactive material or equivalent information; and

(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in chapter 246-246 WAC. The licensee shall, as appropriate:

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per (~~one hundred~~) 100 square centimeters—removable and fixed—for surfaces, megabecquerels

(microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(14) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the department determines that:

(a) Radioactive material has been properly disposed;

(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in chapter 246-246 WAC; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in chapter 246-246 WAC; and

(d) Records required by subsections (16) and (18) of this section have been received.

(15) Specific licenses for uranium and thorium milling are exempt from subsections (6) (d), (9) and (10) of this section with respect to reclamation of tailings impoundments or waste disposal areas.

(16) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than (~~one hundred twenty~~) 120 days, in an unsealed form, shall forward the following records to the department:

(a) Records of disposal required by WAC 246-221-230 (8) (a); and

(b) Records of results required by WAC 246-221-230 (7) (h).

(17) If licensed activities are transferred or assigned in accordance with WAC 246-232-050(2), each licensee authorized to possess radioactive material, with a half-life greater than (~~one hundred twenty~~) 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(a) Records of disposal required by WAC 246-221-230 (8) (a); and

(b) Records of results required by WAC 246-221-230 (7) (h).

(18) Prior to license termination, each licensee shall forward the records required by WAC 246-235-075(6) to the department.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-060, filed 11/22/13, effective 12/23/13; WSR 04-04-055, § 246-232-060, filed 1/30/04, effective 3/1/04; WSR 00-07-085, § 246-232-060, filed 3/15/00, effective 4/15/00; WSR 99-15-105, § 246-232-060, filed 7/21/99, effective 8/21/99. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 97-08-095, § 246-232-060, filed 4/2/97, effective 5/3/97; WSR 91-15-112 (Order 184), § 246-232-060, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-060, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-19-330, filed 9/16/83.]

AMENDATORY SECTION (Amending WSR 13-24-025, filed 11/22/13, effective 12/23/13)

WAC 246-232-080 Transfer of material. (1) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(2) Except as otherwise provided in the license and subject to the provisions of this section, a licensee may transfer radioactive material:

(a) To the department. A licensee may transfer material to the department only after receiving prior approval from the department;

(b) To the United States Department of Energy;

(c) To a person exempt from the rules in this part to the extent permitted under such exemption;

(d) To a person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the department, the NRC or an agreement state, or to a person otherwise authorized to receive such material by the federal government or an agency thereof, the department, or an agreement state; or

(e) As otherwise authorized by the department in writing.

(3) Before transferring radioactive material to a specific licensee of the department, the NRC or an agreement state, or to a general licensee who is required to register with the department, the NRC or an agreement state prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(4) The following methods for the verification required by subsection (3) of this section are acceptable:

(a) The transferor may obtain for possession, and read, a current copy of the transferee's specific license or registration certificate;

(b) The transferor may obtain for possession a written certification from the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(c) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date: Provided, That the oral certification is confirmed in writing within (~~ten~~) 10 days;

(d) The transferor may obtain other sources of information compiled by a reporting service from official records of the department, the NRC or the licensing agency of an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(e) When none of the methods of verification described in subsection (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the NRC or the licensing agency of an agreement state that the transferee is licensed to receive the radioactive material.

- (5) Preparation for shipment and transport of radioactive material must be in accordance with the provisions of WAC 246-232-090.
- (6) The requirements of subsection (4) of this section notwithstanding, no verification is required when returning used, unused or decayed sources of radiation to the original manufacturer, (e.g., industrial radiography sources, high dose-rate afterloader sources, tel-etherapy sources, portable moisture/density gauge sources, fixed gauge sources, and Mo-99/Tc-99m or Rb-82/Sr-82 generators).

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-080, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-232-080, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-19-400, filed 12/11/86. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-19-400, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-19-400, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-170.]

SCHEDULES

AMENDATORY SECTION (Amending WSR 16-13-054, filed 6/10/16, effective 7/11/16)

WAC 246-232-130 Schedule C, exempt concentrations. (See WAC 246-232-010 (1) .)

Element (atomic number)	Radionuclide	Column I Gas concentration µCi/ml ¹	Column II Liquid and solid concentration µCi/ml ²
Antimony (51)	Sb-122		3x10 ⁻⁴
	Sb-124		2x10 ⁻⁴
	Sb-125		1x10 ⁻³
Argon (18)	Ar-37	1x10 ⁻³	
	Ar-41	4x10 ⁻⁷	
Arsenic (33)	As-73		5x10 ⁻³
	As-74		5x10 ⁻⁴
	As-76		2x10 ⁻⁴
	As-77		8x10 ⁻⁴
Barium (56)	Ba-131		2x10 ⁻³
	Ba-140		3x10 ⁻⁴
Beryllium (4)	Be-7		2x10 ⁻²
Bismuth (83)	Bi-206		4x10 ⁻⁴
Bromine (35)	Br-82	4x10 ⁻⁷	3x10 ⁻³

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci}/\text{ml}^1$	Column II Liquid and solid concentration $\mu\text{Ci}/\text{ml}^2$
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152 (9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-125	3×10^{-9}	2×10^{-5}
	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci}/\text{ml}^1$	Column II Liquid and solid concentration $\mu\text{Ci}/\text{ml}^2$
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85		3×10^{-6}
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-3}
Neodymium (60)	Nd-147		6×10^{-4}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-3}
Osmium (76)	Os-185		7×10^{-4}
	Os-191m		3×10^{-2}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
Palladium (46)	Pd-103		3×10^{-3}
	Pd-109		9×10^{-4}
Phosphorus (15)	P-32		2×10^{-4}
Platinum (78)	Pt-191		1×10^{-3}
	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
Potassium (19)	K-42		3×10^{-3}
Praseodymium (59)	Pr-142		3×10^{-4}
	Pr-143		5×10^{-4}
Promethium (61)	Pm-147		2×10^{-3}
	Pm-149		4×10^{-4}
Radium (88)	Ra-226		1×10^{-7}
	Ra-228		3×10^{-7}
Rhenium (75)	Re-183		6×10^{-3}
	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
Rhodium (45)	Rh-103m		1×10^{-1}
	Rh-105		1×10^{-3}
Rubidium (37)	Rb-86		7×10^{-4}

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci}/\text{ml}^1$	Column II Liquid and solid concentration $\mu\text{Ci}/\text{ml}^2$
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
Scandium (21)	Sc-46		4×10^{-4}
	Sc-47		9×10^{-4}
	Sc-48		3×10^{-4}
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}^1$	Column II Liquid and solid concentration $\mu\text{Ci/ml}^2$
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta or gamma emitting radioactive material not listed above with half-life less than ((3)) <u>three</u> years		1×10^{-10}	1×10^{-6}

- Notes: ¹ Values are given in Column I only for those materials normally used as gases
² $\mu\text{Ci/gm}$ for solids
- Note 1: Many radionuclides decay into nuclides which are also radioactive. In expressing the concentrations in Schedule C the activity stated is that of the parent nuclide and takes into account the daughters.
- Note 2: For purposes of WAC 246-232-010(1) where there is involved a combination of nuclides, the limit for the combination should be derived as follows: Determine for each nuclide in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific nuclide when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Nuclide A in Product}}{\text{Exempt concentration of Nuclide A}} + \frac{\text{Concentration of Nuclide B in Product}}{\text{Exempt concentration of Nuclide B}} \leq 1$$

- Note 3: For the purpose of determining concentration in a product or device, the total quantity of radioactive material present is divided by only that weight or volume of the discrete part or component throughout which the radioactive material is relatively uniformly distributed. If the weight or volume of this part or component cannot be determined then the product or device should be evaluated on the basis of the total quantity of radioactive material present.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-232-130, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-232-130, filed 11/22/13, effective 12/23/13; WSR 01-02-068, § 246-232-130, filed 12/29/00, effective 1/29/01. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-232-130, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-130, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-19-580, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-19-580,

filed 9/16/83; WSR 79-12-073 (Order 1459), § 402-19-580, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-250.]

AMENDATORY SECTION (Amending WSR 09-06-003, filed 2/18/09, effective 3/21/09)

WAC 246-232-140 Schedule D.

ACCEPTABLE SURFACE CONTAMINATION LEVELS

NUCLIDES A	AVERAGE B C F	MAXIMUM B D F	REMOVABLE B E F WIPE LIMITS
U-nat, U-235, U-238, and associated decay products	5,000 dpm/100 cm ²	15,000 dpm/100 cm ²	1,000 dpm α/100 cm ²
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	100 dpm/100 cm ²	300 dpm/100 cm ²	20 dpm/100 cm ²
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	1000 dpm/100 cm ²	3000 dpm/100 cm ²	200 dpm/100 cm ²
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except SR-90 and others noted above	5000 dpm/100 cm ²	15,000 dpm/100 cm ²	1000 dpm βγ/100 cm ²

- A Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha-and beta-gamma-emitting nuclides should apply independently.
- B As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- C Measurements of average contaminant should not be averaged over more than ((±)) one square meter. For objects of less surface area, the average should be derived for each such object.
- D The maximum contamination level applies to an area of not more than 100 cm².
- E The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
- F The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr at ((±)) one cm and 1.0 mrad/hr at ((±)) one cm, respectively, measured through not more than ((7)) seven milligrams per square centimeter of total absorber.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-232-140, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-232-140, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-19-590, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-19-590, filed 9/16/83.]

FEES

OTS-3843.3

AMENDATORY SECTION (Amending WSR 17-01-034, filed 12/12/16, effective 1/12/17)

WAC 246-235-010 Filing application for specific licenses. (1) ~~((Applications for))~~ An applicant applying for a specific license ~~((s must be filed on))~~ shall submit an application on a department approved form ~~((RHF-1))~~.

(2) The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's behalf.

(4) ~~((An application for a license may include a request for a license authorizing one or more activities.))~~ An applicant may apply on one application for multiple licenses authorizing other activities under chapters 246-220 through 246-254 WAC and under chapter 70A.388 RCW, provided that the application specifies the activities for which licenses are requested.

(5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the department provided such references are clear and specific.

(6) ~~(a)~~ Except as provided in ~~((e), (d), and (e))~~ (b), (c), and (d) of this subsection, an application for a specific license to use radioactive materials in the form of a sealed source or in a device that contains the sealed source must:

~~((a))~~ (i) Identify the source or device by manufacturer and model number as registered with the department under WAC 246-235-108, the NRC under 10 C.F.R. 32.210, an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 C.F.R. 32.210; or

~~((b))~~ (ii) Contain the information identified in WAC 246-235-108(3) ~~((; or))~~.

~~((e))~~ (b) For sources or devices manufactured before October 23, 2012, that are not registered with the NRC under 10 C.F.R. 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in WAC 246-235-108(3), the application must include:

(i) All available information identified in WAC 246-235-108(3) concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of ~~((the most))~~ a recent leak test.

~~((d))~~ (c) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with WAC 246-235-108 (7)(a), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

~~((e))~~ (d) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used, and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(7) Applications and documents submitted to the department may be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(8) As provided by WAC 246-235-075, certain applications for specific licenses filed under chapters 246-220 through 246-254 WAC must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

(9) An application from a medical facility, educational institution, or federal facility to produce positron emission tomography radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under chapter 246-240 WAC must include:

(a) A request for authorization for the production of positron emission tomography radionuclides or evidence of an existing license issued under chapters 246-220 through 246-254 WAC for a positron emission tomography radionuclide production facility within its consortium from which it receives positron emission tomography radionuclides.

(b) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in WAC 246-235-100 (1)(b).

(c) Identification of individuals authorized to prepare the positron emission tomography radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in WAC 246-235-100 (2)(b).

(d) Information identified in WAC 246-235-100 (1)(c) on the positron emission tomography drugs to be noncommercially transferred to members of its consortium.

(10) An application for a license to receive and possess radioactive material for the conduct of any activity which the department has determined will significantly affect the quality of the environment must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any environmental report required under WAC 246-235-086, chapter 197-11, or 246-03 WAC.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-010, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-010, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-010, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-010, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-010, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-020, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-050.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-020 General requirements for the issuance of specific licenses. ~~((A license application will be approved if the department determines that:))~~ Upon a determination that an application meets the requirements of this section, chapters 70A.388 RCW and 246-220 through 246-254 WAC, the department will issue a specific license authorizing the possession and use of radioactive material.

~~(1)~~ (1) The application is for a purpose authorized by chapter 70A.388 RCW;

~~(2)~~ (2) The applicant is qualified by ((reason of)) training and experience to use the material ((in question)) for the purpose requested ((in accordance with these regulations in a manner to minimize danger to public)) in such manner as to protect health and safety and minimize danger to life or property;

~~((2))~~ (3) The applicant's proposed equipment, facilities, and procedures are adequate to ((minimize danger to public)) protect health and safety and minimize danger to life or property;

~~((3))~~ (4) The issuance of the license will not harm the health and safety of the public; ((and

~~(4))~~ (5) The applicant satisfies any applicable special requirements in ((WAC 246-235-075 through 246-235-110, and chapters 246-240 through 246-252 WAC.

~~(5) When))~~ chapters 246-220 through 246-254 WAC; and

(6) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, uranium enrichment facility construction and operation, production of uranium hexafluoride, or for the conduct of any other activity which the department determines will significantly affect the quality of the environment, the applicant may not begin construction until the department has weighed the environmental, economic, technical, and other benefits against the environmental costs, and, considering available alternatives, has concluded that the issuance of the license is appropriate, with any appropriate conditions to protect environmental values. Commencement of construction prior to approval by the department shall be grounds for denial of a license to receive and possess radioactive material in the plant or facility. Commencement of construction as defined in chapter 246-220 WAC may include nonconstruction activities if the activity has a reasonable nexus to radiological safety and security.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-020, filed 2/23/15, effective 3/26/15; WSR 06-05-019, § 246-235-020, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-235-020, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-020, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-040, filed 12/11/86. Statutory Authority: Chapter 70.121 RCW. WSR 81-16-031 (Order 1683), § 402-22-040, filed 7/28/81. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-040, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-060.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-075 Financial assurance and recordkeeping for decommissioning. (1) Each applicant for one of the following licenses shall submit a decommissioning funding plan as described in this section:

(a) A specific license authorizing receipt of radioactive waste for the purpose of volume reduction, repackaging or interim storage.

(b) Receipt of contaminated articles, scrap material, equipment, or clothing to be decontaminated at the licensee's facility.

(c) A specific license authorizing the possession and use of radioactive material of half-life greater than ~~((one hundred twenty))~~ 120 days and in quantities for unsealed material exceeding 10^3 times and for sealed forms exceeding 10^{10} times the applicable quantities set forth in WAC 246-221-300 Appendix B (for a combination of nuclides the unity rule applies. A decommissioning funding plan will be required if R is greater than 1, where R is defined as the sum of the ratios of the quantity for sealed and unsealed forms of each nuclide compared to the applicable value derived from WAC 246-221-300).

(d) A specific license authorizing possession and use of source material in readily dispersible form and in quantities greater than 370 megabecquerels (10 millicuries).

(2) Each decommissioning funding plan must be submitted for review and approval and must contain the following:

(a) A description of the facility and areas within the facility likely to require decommissioning as a result of routine operation.

(b) A description of methods and general procedures for performing facility decontamination, maintaining security, and performing a final radiation survey.

(c) A detailed cost estimate for decommissioning facilities impacted by the activities authorized in the specific license reflecting:

(i) The cost of an independent contractor to perform all decommissioning activities;

(ii) The cost of meeting WAC 246-246-020, Radiological criteria for unrestricted use, or the cost of meeting WAC 246-246-030, Criteria for license termination under restricted conditions, and WAC 246-246-040, Alternate criteria for license termination;

(iii) Any previous spills of radioactive material;

(iv) An adequate contingency factor;

(v) A means for adjusting cost estimates and associated funding levels periodically over the life of the facility or facilities;

(vi) Anticipated labor, equipment, and material costs;

(vii) Anticipated waste volume;

(viii) Anticipated volume of on-site subsurface material containing residual radioactivity requiring remediation or disposal;

(ix) Anticipated packaging, transportation, and waste disposal cost of decommissioning;

(x) Routine costs for packaging, transportation, and waste disposal;

(xi) On-site disposal; and

(xii) Use of settling or evaporation ponds.

(d) A description of the method of assuring funds for decommissioning, pursuant to subsection (4) of this section, including means

for adjusting levels periodically over the life of the facility or facilities.

(e) Identification of and justification for the key assumptions used and applied in the decommissioning cost estimate.

(f) A commitment to clean up accidental spills promptly and to begin decommissioning of the facility or facilities within ~~((twelve))~~ 12 months of ceasing operation involving radioactive material.

(3) Each cost estimate for decommissioning must include identification and justification of all key assumptions used in the plan and cost estimate.

(4) Each applicant shall submit a certification that financial assurance for decommissioning meets the amount of the approved decommissioning cost estimate prior to commencement of the use of any radioactive materials. The applicant or licensee shall provide a signed original of the financial instrument obtained to satisfy the financial surety requirement unless a previously submitted and accepted financial instrument continues to cover the plan and cost estimate for decommissioning. That financial instrument must be one or more of the following approved methods:

(a) Prepayment. Prepayment is the deposit of sufficient funds to pay decommissioning costs. Funds must be deposited prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The funding must be stipulated specifically for the purpose of decommissioning.

(b) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless ~~((ninety))~~ 90 days or more prior to the renewal date, the issuer notifies the department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also require that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within ~~((thirty))~~ 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. Funds must be placed into a trust segregated from the licensee's assets, outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent real rate of return on investment. The trustee and trust must be acceptable to the department. Acceptable trustees include an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(iii) The surety method or insurance must remain in effect until the department has terminated the license.

(c) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking

fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control. The total amount of funds in the external sinking fund must be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in subsection (4)(b) of this section.

(d) Statement of intent. In the case of state or local government licensees, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) Other methods of financial assurance as approved by the department. The department may approve other financial mechanisms submitted by the applicant or licensee if the alternate method meets, at a minimum, the requirements of 10 C.F.R. 30.35 and associated NRC guidance.

(5)(a) The applicant or licensee shall submit to the department for approval, an initial or updated decommissioning funding plan with a detailed cost estimate prior to license issuance and shall submit an updated plan at intervals not to exceed three years.

(b) The decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. The amount of the financial assurance may not be adjusted downward until the updated decommissioning funding plan is approved. The information submitted with the original or prior approved decommissioning funding plan must be updated and submitted with the adjusted decommissioning funding plan. It must specifically address the effect of the following events on decommissioning costs:

- (i) Facility modifications;
- (ii) Changes in authorized possession limits;
- (iii) Changes in process;
- (iv) Spills of radioactive material and actual remediation costs that exceed the previous cost estimate;
- (v) Spills of radioactive material producing additional residual radioactivity in on-site subsurface material;
- (vi) Waste inventory increase above the amount previously estimated;
- (vii) Waste disposal costs increase above the amount previously estimated;
- (viii) On-site disposal;
- (ix) Use of settling or evaporation ponds; and
- (x) Any alteration which might affect the overall cost of decommissioning.

(c) The applicant or licensee shall incorporate department comments into the decommissioning funding plan including its cost estimate and shall revise its financial surety accordingly.

(d) Applicants shall obtain the appropriate financial assurance as approved by the department prior to receipt of licensed material. The department may issue a new license if the applicant agrees to comply with the decommissioning funding plan as approved. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of this section must be submitted to the department before receipt of licensed material.

(e) Licensees shall implement the financial assurance requirements within (~~(thirty)~~) 30 days of receiving department approval of the initial or updated decommissioning funding plan. Licensees shall submit copies of the financial surety within (~~(thirty)~~) 30 days of securing the surety and annually thereafter.

(6) Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with WAC 246-232-050(2), licensees shall transfer all records described in this subsection to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated by the department. If records of relevant information are kept for other purposes, reference to these records and their locations may be used.

(a) 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.

(b) Information the department considers important to decommissioning consists of:

(i) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, including subsurface residual radioactivity. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(ii) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(iii) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or depleted uranium used only for shielding or as penetrators in unused munitions, or radioactive materials having only half-lives of less than (~~(sixty-five)~~) 65 days, a list contained in a single document and updated every two years, of the following:

(A) All areas designated and formerly designated as restricted areas as defined under WAC 246-220-010;

(B) All areas outside of restricted areas that require documentation under (b)(i) of this subsection;

(C) All areas outside of restricted areas where current and previous wastes have been buried as documented under WAC 246-221-230

(8) (a); and

(D) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in chapter 246-246 WAC or apply for approval for disposal under WAC 246-221-180. Records of the cost estimate performed for the decommiss-

sioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-075, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-075, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.095 and 70.98.050. WSR 07-03-049, § 246-235-075, filed 1/12/07, effective 2/12/07. Statutory Authority: RCW 70.98.050. WSR 00-07-085, § 246-235-075, filed 3/15/00, effective 4/15/00; WSR 99-15-105, § 246-235-075, filed 7/21/99, effective 8/21/99. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 97-08-095, § 246-235-075, filed 4/2/97, effective 5/3/97; WSR 92-06-008 (Order 245), § 246-235-075, filed 2/21/92, effective 3/23/92.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-077 Special requirements for emergency planning.

(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in WAC 246-235-150, "Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release," must contain either:

(a) An evaluation showing that the maximum dose to a ~~((member of the public))~~ person off-site due to a release of radioactive materials would not exceed ~~((±))~~ one rem effective dose equivalent or ~~((5))~~ five rems to the thyroid ~~((or an intake of 2 milligrams of soluble uranium))~~; or

(b) An emergency plan for responding to ~~((the radiological hazards of an accidental))~~ a release of radioactive material ~~((and to the chemical hazards associated with uranium hexafluoride, when present))~~.

(2) One or more of the following factors may be used to support an evaluation submitted under subsection (1)(a) of this section:

(a) The radioactive material is physically separated so that only a portion could be involved in an accident;

(b) All or part of the radioactive material is not subject to re-release during an accident because of the way it is stored or packaged;

(c) The release fraction in the respirable size range would be lower than the release fraction listed in WAC 246-235-150 Schedule C due to the chemical or physical form of the material;

(d) The solubility of the radioactive material would reduce the dose received;

(e) Facility design or engineered safety features in the facility would cause the release fraction to be lower than listed in WAC 246-235-150 Schedule C;

(f) Operating restrictions or procedures would prevent a release fraction as large as that listed in WAC 246-235-150 Schedule C; or

(g) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under subsection (1)(b) of this section must include the following information:

(a) Facility description. A brief description of the licensee's facility and area near the site.

- (b) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.
- (c) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.
- (d) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
- (e) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment.
- (f) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.
- (g) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the department; also responsibilities for developing, maintaining, and updating the plan.
- (h) Notification and coordination. A commitment ~~((7))~~ to and a brief description of the means ~~((available,))~~ to promptly ~~((to))~~ notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee must also commit to notify the department immediately after notification of the appropriate off-site response organizations and not later than one hour after the licensee declares an emergency. These reporting requirements do not supersede or release licensees from complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.
- (i) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the department.
- (j) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
- (k) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.
- (l) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the spe-

cific site, and the scenarios must not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(m) Hazardous chemicals. A certification that the licensee or applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the licensee's or applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the off-site response organizations expected to respond in case of an accident (~~(sixty)~~) 60 days to comment on the licensee's emergency plan before submitting it to the department. The licensee shall provide any comments received within the (~~(sixty)~~) 60 days to the department with the emergency plan.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-077, filed 2/23/15, effective 3/26/15; WSR 95-01-108, § 246-235-077, filed 12/21/94, effective 1/21/95.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-080 Special requirements for possession and use of medical calibration and reference sources. (1) Leak tests.

(a) Any licensee or registrant who possesses sealed sources as calibration or reference sources must test for leakage or contamination each sealed source containing radioactive material, other than Hydrogen-3, with a half-life greater than (~~(thirty)~~) 30 days in any form other than gas at least every six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed sources must not be used until tested. However, leak tests are not required when: The source contains 3.7 megabecquerels (100 microcuries) or less of beta or gamma emitting material or 370 kilobecquerels (10 microcuries) or less of alpha emitting material or the sealed source is stored and is not being used: Provided, a physical inventory of the source and wipe surveys of the storage area or storage container are conducted as required by these rules or license condition.

(b) The leak test must be capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample. The test sample must be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results must be kept in units of microcuries and maintained for inspection by the department.

(c) If the leak test reveals the presence of 185 becquerels (0.005 microcurie) or more of removable contamination, the licensee or registrant must immediately withdraw the sealed source from use and must cause it to be decontaminated and repaired or to be disposed of in accordance with chapters 246-235 and 246-221 WAC. The licensee must file a report within five days of the test with the department de-

scribing the equipment involved, the test results, and the corrective action taken.

(2) Any licensee or registrant who possesses and uses calibration and reference sources must:

(a) Follow the radiation safety and handling instructions approved by the department, the NRC or an agreement state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain the instructions in a legible and conveniently available form; and

(b) Conduct a quarterly or semi-annual physical inventory to account for all sources received and possessed. Records of the inventories must be maintained for inspection by the department and must include, at a minimum, the quantities and kinds of radioactive material, location of sources, name of person performing the inventory, and the date of the inventory.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-080, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-080, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-080, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-235-080, filed 2/6/06, effective 3/9/06; WSR 00-08-013, § 246-235-080, filed 3/24/00, effective 4/24/00; WSR 98-13-037, § 246-235-080, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-080, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-070, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-22-070, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-22-070, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-070, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-070.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-086 Special requirements for environmentally significant licensing actions. In addition to the requirements set forth in WAC 246-235-020, a specific license for any activity within the licensing authority of the department which the department determines will significantly affect the radiological quality of the human environment, including those specified in WAC 197-11-845(1) and 246-03-030 (1)(a)(ii) (i.e., licenses to operate low level waste burial facilities or licenses to operate or expand beyond the design capacity, mineral processing facilities or their tailings areas, whose products, or by-products, have concentrations of naturally occurring radioactive material in excess of exempt concentrations as specified in WAC 246-232-130, Schedule C), will be issued if the following conditions are met:

(1) Environmental impact statement.

(a) The application for a license or license amendment (other than administrative amendments) is accompanied or preceded by a final

environmental impact statement or final declaration of nonsignificance completed in accordance with the SEPA procedures and guidelines specified in chapters 197-11 and 246-03 WAC. For any uranium or thorium mill in operation on or before the effective date of this regulation for which an environmental impact statement has not been prepared previously, an application for license renewal must be accompanied or preceded by a final environmental impact statement or final declaration of nonsignificance completed in accordance with SEPA guidelines. No construction shall be commenced until the license has been issued or unless an emergency exemption from SEPA requirements is granted in accordance with WAC 197-11-880. For the purposes of this subsection, the terms "commencement of construction" and "construction" have the same meaning as that defined in WAC 246-220-010. In the case where an exemption is granted, the applicant shall assume all financial risk for construction activity; waive any claim of entitlement to the issuance of a license based solely upon the grant of the exemption or the commencement of construction pursuant thereto; and furnish, if the circumstances warrant and the department so requires, a financial surety arrangement to ensure the protection of the public health, safety, and the environment in the event of abandonment, default, or inability of the licensed applicant to meet the requirements of the act or these regulations.

((Note: No construction shall be commenced until the license has been issued or unless an emergency exemption from SEPA requirements is granted in accordance with WAC 197-11-880. For the purposes of this subsection, the terms "commencement of construction" and "construction" have the same meaning as that defined in WAC 246-220-010. In the case where an exemption is granted, the applicant shall assume all financial risk for construction activity; waive any claim of entitlement to the issuance of a license based solely upon the grant of the exemption or the commencement of construction pursuant thereto; and furnish, if the circumstances warrant and the department so requires, a financial surety arrangement to insure the protection of the public health, safety and the environment in the event of abandonment, default, or inability of the license applicant to meet the requirements of the act or these regulations.))

(b) In addition to the information required in chapter 197-11 WAC, the following additional areas must be addressed in the final environmental impact statement:

(i) Alternative sites to those chosen by the applicant must include all alternative sites, whether or not those sites are under the control or ownership of the applicant.

(ii) Long-term impacts must include, but not be limited to, decommissioning, decontamination, reclamation impacts and material management associated with the proposed activities.

(iii) Environmental reviews, dose assessments, ecology, construction effects on biota, impact on the environment from the use of chemicals, and socioeconomic effects must be addressed.

(iv) Alternative disposal sites and techniques for disposal must be evaluated to determine if a site or technique is clearly superior.

(2) For uranium or thorium milling operations, a bond made payable to the department of health or other acceptable government agency, and in an amount specified by the department, must be posted to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements for reclamation and disposal of tailings and for decommissioning the site. The bond, or a copy thereof when the bond is made payable to another government agency, must be received by the department prior to issuance of the license, or prior to license renewal for mills in operation on or before the effective date of this regulation. Other acceptable surety arrangements in addition to surety bonding include cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit or combinations of the foregoing. The amount and mechanism of the surety arrangement may be re-

viewed by the department preceding each license renewal and adjustments may be required of the licensee prior to such renewal.

(3) The owner of the proposed uranium or thorium mill and tailings site(s) agrees to transfer or revert to the appropriate state or federal agency upon termination of the license, all lands, buildings and grounds, and any interest therein, necessary to fulfill the purposes of this subsection, except where the lands are held in trust for, or are owned by, any Indian tribe. For any uranium or thorium mill in operation on or before the effective date of this regulation, such an agreement will be required prior to license renewal.

(4) For all uranium and thorium milling operations, the owner or operator shall arrange to pay to the department or its designee a fee in accordance with WAC 246-254-150 for a special security fund for the further maintenance, surveillance or care which may be required after a licensee has ceased to operate.

A minimum fund of (~~two hundred fifty thousand dollars~~) \$250,000 must be provided by the licensee payable to the state. If a shortfall exists between the amount of money in the special security fund and the (~~two hundred fifty thousand dollars~~) \$250,000 minimum amount, a surety bond, or other acceptable surety instrument as defined (~~above~~) in this chapter must be arranged.

(5) The application for a license includes a description of an appropriate program for effluent monitoring, environmental monitoring and data reporting. The description must encompass locations, frequency, and types of sampling, analytical plans and procedures, minimum detection levels, sampling equipment and quality assurance programs.

(6) All licensees or registrants required to meet the additional requirements set forth in this subsection shall establish environmental monitoring programs adequate to determine the impact of their activity on the natural environment around the site of their environmentally significant activity. The established environmental and effluent monitoring program must address all environmentally significant radionuclide releases and external radiation sources caused or threatened to be caused by the licensee's activities.

(a) Effluent and environmental monitoring results must include the following minimum information as pertinent:

(i) Information as to flow rates, total volume of effluent, peak concentration, concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;

(ii) A description of the properties of the effluents, including:

(A) Chemical composition;

(B) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas aerosol for air effluents;

(C) The hydrogen ion concentrations (pH) of liquid effluents; and

(D) The size range of particulates in effluent released into air;

(iii) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent.

(iv) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:

(A) In air at any point of human occupancy; or

(B) In water at points of use downstream from the point of release of the effluent;

(v) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent;

(vi) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release;

(vii) A written description of sampling techniques and sample analysis methods;

(viii) A written description of how all calculated results were obtained from sample analysis data. This explanation must include example calculations and estimates of the precision and sensitivity of monitoring results;

(ix) A written description of the licensee's quality control program including specification of control samples and standard samples used.

(b) The licensee shall submit in writing to the department within (~~sixty~~) 60 days after January 1st and July 1st of each year, reports specifying the quantities of each of the principle radionuclides released to unrestricted areas in liquid and in gaseous effluent during the previous six months of operations. This data must be reported in a manner that will permit the department to confirm the potential annual radiation doses to the public. All data from the radiological and non-radiological environmental monitoring program will also be submitted for the same time period and frequency as specified above. The data must be reported in a manner which will allow the department to confirm the potential annual radiation doses to the public.

(7) For land disposal of radioactive material, the provisions of chapter 246-250 WAC must also be met.

(8) For operation of mineral processing facilities, the provisions of chapter 246-252 WAC must also be met.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-086, filed 2/23/15, effective 3/26/15; WSR 00-08-013, § 246-235-086, filed 3/24/00, effective 4/24/00.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-090 Special requirements for specific licenses of broad scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of these licenses. (~~(*)~~) A person may not introduce radioactive material into a product or material, knowing or having reasons to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC, Washington, D.C. 20555. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing source material, by-product material or radioactive material, whose subsequent possession, use, transfer and disposal by all other persons exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

(*Note: A person may not introduce radioactive material into a product or material, knowing or having reasons to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by NRC, Washington, D.C. 20555. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing source material, by product material or radioactive material, whose subsequent possession, use, transfer and disposal by all other persons exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.)

(1) *The different types of broad licenses are (~~listed below~~):*

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multi-curie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 246-235-140 Schedule B, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in WAC 246-235-140 Schedule B, Column I. If two or more radionuclides are possessed, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in WAC 246-235-140 Schedule B, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 246-235-140 Schedule B, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in WAC 246-235-140 Schedule B, Column II. If two or more radionuclides are possessed, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in WAC 246-235-140 Schedule B, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

(2) *The department will approve an application for a Type A specific license of broad scope if:*

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

(b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The establishment of a radiation safety committee composed of a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(ii) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material;

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the ade-

quacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with item (2)(c)(iii)(B) of this section prior to use of the radioactive material.

(3) *The department will approve an application for a Type B specific license of broad scope if:*

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

(b) The applicant has established administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(ii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material;

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with item (3)(b)(ii)(B) of this section prior to use of the radioactive material.

(4) *The department will approve an application for a Type C specific license of broad scope if:*

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

(b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of individuals, who have received:

(i) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(ii) At least (~~forty~~) 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

(5) *Specific licenses of broad scope are subject to the following conditions:*

(a) Unless specifically authorized by the department, persons licensed under this section shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use or transfer devices containing 3700 terabecquerels (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the department under chapter 246-240 WAC, WAC 246-235-086 or 246-235-091 through 246-235-105 is required; or

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(b) For each Type A specific license of broad scope radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) For each Type B specific license of broad scope radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(d) For each Type C specific license of broad scope radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subsection (4) of this section.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-090, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-090, filed 11/22/13, effective 12/23/13; WSR 06-05-019, § 246-235-090, filed 2/6/06, effective 3/9/06; WSR 00-08-013, § 246-235-090, filed 3/24/00, effective 4/24/00; WSR 98-13-037, § 246-235-090, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-090, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-090, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-090, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-073.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-091 Manufacture and distribution of industrial products containing depleted uranium under general license. (1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to WAC 246-233-010(4) or equivalent regulations of the NRC or an agreement state will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one year a radiation dose in excess of (~~ten~~) 10 percent of the limits specified in WAC 246-221-010(1); and

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasona-

ble assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under this section only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The department may deny any application for a specific license under this section if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to subsection (1) of this section shall:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(b) Label or mark each unit to:

(i) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(ii) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or of an agreement state;

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted uranium";

(d) Furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in WAC 246-233-010(4) or its equivalent:

(i) A copy of the general license contained in WAC 246-233-010(4) and a copy of department Form RHF-20; or

(ii) A copy of the general license contained in the NRC's or agreement state's regulation equivalent to WAC 246-233-010(4) and a copy of the NRC's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in WAC 246-233-010(4) and a copy of department Form RHF-20 with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in WAC 246-233-010(4).

(e) Report to the department all transfers of industrial products or devices to persons for use under the general license in WAC 246-233-010(4). Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within (~~thirty~~) 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under chapter 246-233 WAC during the reporting period, the report must so indicate;

(f) Provide certain other reports as follows:

(i) Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in Section 40.25 of 10 C.F.R. Part 40;

(ii) Report to the responsible department all transfers of devices manufactured and distributed pursuant to this section for use under a general license in that state's regulations equivalent to WAC 246-233-010(4);

(iii) Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within (~~thirty~~) 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

(iv) If no transfers have been made to NRC licensees during the reporting period, this information must be reported to the NRC;

(v) If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information must be reported to the responsible department; and

(g) Keep records showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in WAC 246-233-010(4) or equivalent regulations of the NRC or of an agreement state. The records must be maintained for a period of two years and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-091, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-091, filed 11/22/13, effective 12/23/13; WSR 98-13-037, § 246-235-091, filed 6/8/98, effective 7/9/98.]

AMENDATORY SECTION (Amending WSR 16-13-054, filed 6/10/16, effective 7/11/16)

WAC 246-235-093 Manufacture, assembly or distribution of devices under general license. (1) An application for a specific license to manufacture or initially transfer or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under WAC 246-233-020 or equivalent regulations of the NRC or an agreement state will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of (~~ten~~) 10 percent of the limits specified in the table in WAC 246-221-010(1); and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

- Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 15 centigray (15 rem)
- Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter 200 centigray (200 rem)
- Other organs 50 centigray (50 rem)

(c) Each device bears a durable, legible, clearly visible label or labels approved by the department, which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by nuclide, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(A) The receipt, possession, use and transfer of this device, Model , Serial No. ((Note*)) Name of manufacturer or distributor, are subject to a general license or the equivalent, and the regulations of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

.....
(((f))Name of manufacturer or distributor((f*)))

(B) The receipt, possession, use and transfer of this device, Model , Serial No. ((Note*)) Name of manufacturer or distributor, are subject to a general license or the equivalent, and the rules of an agreement state. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

.....
(((f))Name of manufacturer or distributor((f*)))

((*Note: The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.))

(C) The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(d) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the nuclide and quantity, the words, "CAUTION - RADIOACTIVE MATERIAL," the radiation symbol described in WAC 246-221-120, and the name of the manufacturer or initial distributor;

(e) Each device meeting the criteria of WAC 246-233-020 (3)(k), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION - RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in WAC 246-221-120;

(f) The device has been registered in the sealed source and device registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

- (a) Primary containment (source capsule);
- (b) Protection of primary containment;
- (c) Method of sealing containment;
- (d) Containment construction materials;
- (e) Form of contained radioactive material;
- (f) Maximum temperature withstood during prototype tests;
- (g) Maximum pressure withstood during prototype tests;
- (h) Maximum quantity of contained radioactive material;
- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under WAC 246-233-020, or under equivalent regulations of the NRC or an agreement state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a radiation dose in excess of (~~ten~~) 10 percent of the limits specified in the table in WAC 246-221-010(1).

(4) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to generally licensed persons must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. If transfer is through an intermediate person, the information must also be provided to the intended user before initial transfer to the intermediate person.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in WAC 246-233-020, the required information must include:

(i) A copy of the general license contained in WAC 246-233-020. If WAC 246-233-020 (3)(b), (c), and (d) or (k) do not apply, those subsections may be omitted;

(ii) A copy of WAC 246-232-050, 246-221-230, 246-221-240, and 246-221-250;

(iii) A list of the services that can only be performed by a specific licensee; and

(iv) Information on acceptable disposal options including estimated costs of disposal; and

(v) An indication that the NRC's policy is to issue high civil penalties for improper disposal.

(b) If a device containing radioactive material is to be transferred for use in another jurisdiction under a general license equivalent to WAC 246-233-020, the required information must include:

(i) A copy of the appropriate NRC or an agreement state's regulations, equivalent to WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250. If a copy of WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250 is provided to a prospective general licensee in lieu of the NRC's or the agreement state's regulations, it must be accompanied by a note explaining that the use of the device is regulated by the NRC or the agreement state. If certain subsections do not apply to the particular device, those subsections may be omitted;

(ii) A list of the services that can only be performed by a specific licensee;

(iii) Information on acceptable disposal options including estimated cost of disposal;

(iv) The name or title, address, and phone number of the contact at the appropriate NRC or an agreement state regulatory agency from which additional information may be obtained; and

(v) An indication that NRC policy is to issue high civil penalties for improper disposal;

(c) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under WAC 246-233-020 must report to the department all transfers of devices to persons for use under the general license in WAC 246-233-020 and all receipts of devices from persons licensed under WAC 246-233-020.

(i) Each report must be clear and legible and contain all of the data required. The required information for transfers to general licensees includes:

(A) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee must be included with information on the actual location of use;

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The manufacturer or initial transferor, the type, model number and serial number of the device transferred; and

(E) The source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the inten-

ded user and each intermediate person, clearly identify and designate each intermediate person by name, address, contact, and relationship to the intended user.

(iii) For devices received from a general licensee under WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received; and the source serial(s), nuclide(s), activity, and date(s) of original activity of radioactive material contained in the device;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a person generally licensed under WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(v) If no transfers have been made to or from persons generally licensed under WAC 246-233-020 during the reporting period, the report must so indicate.

(vi) The report must cover each calendar quarter, must clearly indicate the period covered by the report, and must be filed within (~~(thirty)~~) 30 days of the end of the calendar quarter.

(vii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(d) Reports to NRC or an agreement state regulatory agency.

(i) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under the NRC's regulations equivalent to WAC 246-233-020 must report to the NRC all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 246-233-020.

(ii) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to persons generally licensed under an agreement state's regulations equivalent to WAC 246-233-020 must report to the agreement state's regulatory authority all transfers of devices to persons for use under a general license equivalent to WAC 246-233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 243-233-020.

(iii) Such report must be clear and legible and contain all of the data required. The required information for transfers to general licenses must include:

(A) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee must be submitted along with information on the actual location of use;

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The type, model number and serial number of the device transferred; and

(E) The quantity and type of radioactive material contained in the device.

(iv) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(v) For devices received from persons generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, the report must include:

(A) The identity of the general licensee by name and address;

(B) The type, model number, and serial number of the device received;

(C) The date of receipt; and

(D) In the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(vi) If the licensee makes changes to a device possessed by a person generally licensed under NRC's or an agreement state's regulations equivalent to WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(vii) The report must cover each calendar quarter, must be filed within (~~thirty~~) 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(viii) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(ix) If no transfers have been made to or from NRC licensees during the reporting period, this information must be reported to the NRC.

(x) If no transfers have been made to or from general licensees within an agreement state during the reporting period, this information must be reported to the responsible agreement state agency upon request of the agency.

(e) The person shall maintain all information and keep records concerning transfers and receipts of devices that support the reports required by this section. Records required by this section must be maintained for a period of three years following the date of the recorded event.

(f) If a notification of bankruptcy has been made under WAC 246-233-050 or the license is to be terminated, each person licensed under this section shall provide, upon request, to the department, the NRC or an agreement state, records of final disposition required under (e) of this subsection.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-235-093, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-093, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-093, filed 11/22/13, effective 12/23/13; WSR 04-04-055, § 246-235-093, filed 1/30/04, effective 3/1/04; WSR 98-13-037, § 246-235-093, filed 6/8/98, effective 7/9/98.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-100 Manufacture, (~~production,~~) preparation, or transfer for commercial distribution of (~~radiopharmaceuticals~~) radioactive drugs containing radioactive material for medical use under chapter 246-240 WAC. (1) An application for a specific license to

manufacture, (~~produce,~~) prepare, or transfer for commercial distribution (~~radiopharmaceuticals~~) radioactive drugs containing radioactive material for use by persons (~~licensed under~~) authorized pursuant to 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~~) of at least one of the following:

(i) Is registered (~~or licensed~~) with the United States Food and Drug Administration (~~(FDA) as a drug manufacturer, preparer, propagator, compounder or processor~~) 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. 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) 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 (~~a state agency~~) the Washington state pharmacy quality assurance commission.

(c) The applicant submits information on the radionuclide(~~(τ))~~

; the chemical and physical form(~~(τ))~~; the maximum activity per vial, syringe, generator, or other container of the (~~radiopharmaceutical,~~) radioactive drug; and the shielding provided by the packaging (~~of the radioactive material which~~) to show it is appropriate for the safe handling and storage of (~~radiopharmaceuticals~~) the radioactive drugs by medical use licensees; and

(d) The applicant (~~satisfies~~) commits to 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~~) 100 days, the time may be omitted(~~(τ)).~~

~~(iii))~~ (ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for com-

mercial distribution. The label must include the radiation symbol, the words "caution-radioactive material" or "danger-radioactive material" and an identifier that ~~((allows))~~ ensures that the syringe, vial, or other container ~~((to))~~ can 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 radio-nuclides 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))~~ (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 ((radiopharmaceuticals)) radioactive drugs for medical use, as defined in WAC 246-240-010, provided that the ((radio-pharmaceutical)) radioactive drug is prepared by ((or under the supervision of)) 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 Pharmacy Quality Assurance Commission requirements in WAC 246-903-030, Nuclear pharmacists, and))~~ 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 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((7)); 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 ((as of December 1, 2008)) before August 8, 2009.~~

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

~~((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)) (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 ((FDA,)) United States Food and Drug Administration requirements, other federal requirements, and state requirements governing ((radiopharmaceuticals)) radioactive drugs.

[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.]

AMENDATORY SECTION (Amending WSR 15-06-015, filed 2/23/15, effective 3/26/15)

WAC 246-235-103 Prototype tests for manufacture of calibration or reference sources containing americium-241 or radium-226. An applicant for a license under this chapter shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of no less than five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

(1) *Initial measurement.* The quantity of radioactive material deposited on the source must be measured by direct counting of the source.

(2) *Dry wipe test.* The entire radioactive surface of the source must be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source must be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(3) *Wet wipe test.* The entire radioactive surface of the source must be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source must be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity remaining on the source following the wet wipe.

(4) *Water soak test.* The source must be immersed in water at room temperature for a period of ((twenty-four)) 24 consecutive hours. The source must then be removed from the water. Removal of radioactive material from the source must be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(5) *Dry wipe test.* On completion of the preceding test in this section, the dry wipe test described in subsection (2) of this section must be repeated.

(6) *Observations.* Removal of more than 0.005 microcurie (185 becquerels) of radioactivity in any test prescribed by this section must be cause for rejection of the source design. Results of prototype tests submitted to the department or the NRC must be given in terms of radioactivity in microcuries (or becquerels) and percent of removal from the total amount of radioactive material deposited on the source.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-103, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-103, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-103, filed 2/18/09, effective 3/21/09.]

AMENDATORY SECTION (Amending WSR 17-01-034, filed 12/12/16, effective 1/12/17)

WAC 246-235-108 Sealed source and device registration and inactivation. (1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the department for evaluation of radiation safety information about its product and for its registration.

(2) Request for review must be sent to the department by an appropriate method, such as hard copy, properly signed electronic document, or fax.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The department normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the department formulates reasonable standards and criteria with the help of the manufacturer or distributor. The department shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. 10 C.F.R. 32 Subpart A includes specific criteria that apply to certain exempt products, Subpart B includes specific criteria applicable to certain generally licensed devices, and Subpart C includes specific provisions that apply to certain specifically licensed items.

(5) After completion of the evaluation, the department issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

(7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(a) Calibration and reference sources containing no more than:

(i) ((37)) Thirty-seven megabecquerels (one millicurie) for beta or gamma emitting radionuclides; or

(ii) 0.37 megabecquerels (ten microcuries), for alpha emitting radionuclides; or

(b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses and:

(i) The intended recipients are licensed under WAC 246-235-090 of this chapter, 10 C.F.R. 33, or comparable provisions of an agreement state;

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 gigabecquerels (20 curies) of tritium (H-3) or 7.4 gigabecquerels (200 millicuries) of any other radionuclide.

(8) After the certificate is issued, the department may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the department will complete its evaluation in accordance with criteria specified in this section. The department may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

(9) (a) A certificate holder who no longer manufactures or initially transfers any of the sealed sources or devices covered by a particular certificate issued by the department shall request inactivation of the registration certificate from the department. Such a request must be made to the department by an appropriate method and must normally be made no later than two years after initial distribution of all of the sources or devices covered by the certificate has ceased. However if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within ((~~ninety~~)) 90 days of this determination and briefly describe the circumstances of the delay.

(b) If a distribution license is to be terminated in accordance with chapters 246-232, 246-233, and 246-235 WAC, the licensee shall request inactivation of its registration certificates associated with that distribution license before the department will terminate the license. Such a request for inactivation of certificates must indicate

that the license is being terminated and include the associated specific license number.

(c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-108, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-108, filed 6/10/16, effective 7/11/16.]

OTS-3881.2

GENERAL PROVISIONS

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-010 Definitions, abbreviations, and acronyms. The definitions, abbreviations, and acronyms in this section and in WAC 246-220-010 apply throughout this chapter unless the context clearly indicates otherwise.

(1) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

(2) "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

(3) "Associate radiation safety officer" means an individual who:

(a) Meets the requirements in WAC 246-240-069 and 246-240-081;

and

(b) Is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

(i) A specific medical use license issued by the department, NRC, or an agreement state; or

(ii) A medical use permit issued by an NRC master material licensee.

(4) "Attestation" means written certification under oath.

~~((4))~~ (5) "Authorized medical physicist" means an individual who:

(a) Meets the requirements in WAC 246-240-072 and 246-240-081; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

- (i) A specific medical use license issued by the department, NRC, or an agreement state;
 - (ii) A medical use permit issued by ((a)) an NRC master material licensee;
 - (iii) A permit issued by ((a)) an NRC or agreement state broad scope medical use licensee; or
 - (iv) A permit issued by ((a)) an NRC master material license broad scope medical use permittee.
- ((5)) (6) "Authorized nuclear pharmacist" means a pharmacist who:
- (a) Meets the requirements in WAC 246-240-075 and 246-240-081; or
 - (b) Is identified as an authorized nuclear pharmacist on:
 - (i) A specific license issued by the department, NRC, or an agreement state, that authorizes medical use or the practice of nuclear pharmacy;
 - (ii) A permit issued by ((a)) an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - (iii) A permit issued by ((a)) an NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
 - (iv) A permit issued by ((a)) an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
 - (c) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
 - (d) Is designated as an authorized nuclear pharmacist in accordance with WAC 246-235-100(2).
- ((6)) (7) "Authorized user" means a physician, dentist, or podiatrist who:
- (a) Meets the requirements in WAC 246-240-081 and 246-240-154, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-278, 246-240-301, or 246-240-399; or
 - (b) Is identified as an authorized user on:
 - (i) A department, NRC, or agreement state license that authorizes the medical use of radioactive material; or
 - (ii) A permit issued by ((a)) an NRC master material licensee that is authorized to permit the medical use of radioactive material; or
 - (iii) A permit issued by a department, NRC, or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or
 - (iv) A permit issued by ((a)) an NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.
- ((7)) (8) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.
- ((8)) (9) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.
- ((9)) (10) "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with WAC 246-240-125.

~~((10))~~ (11) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 mega-electron volts and is commonly used for production of short half-life radionuclides for medical use.

~~((11))~~ (12) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

~~((12))~~ (13) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

~~((13))~~ (14) "FDA" means the U.S. Food and Drug Administration.

~~((14))~~ (15) "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

~~((15))~~ (16) "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to ~~((2))~~ two gray (200 rads) per hour at the point or surface where the dose is prescribed.

~~((16))~~ (17) "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or that person's delegate or delegates.

~~((17))~~ (18) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

~~((18))~~ (19) "Medical event" means an event that meets the criteria in WAC 246-240-651.

~~((19))~~ (20) "Medical institution" means an organization in which more than one medical discipline is practiced.

~~((20))~~ (21) "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

~~((21))~~ (22) "Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than ~~((2))~~ two gray (200 rads), but less than or equal to 12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

~~((22))~~ (23) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

~~((23))~~ (24) "Ophthalmic physicist" means an individual who:

(a) Meets the requirements in WAC 246-240-272 (1)(b) and 246-240-081; and

(b) Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the NRC or an agreement state;

(ii) Permit issued by an NRC or agreement state broad scope medical use licensee;

(iii) Medical use permit issued by an NRC master material licensee; or

(iv) Permit issued by an NRC master material licensee broad scope medical use permittee.

(25) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source

or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

~~((24))~~ (26) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

~~((25))~~ (27) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

~~((26))~~ (28) "Positron emission tomography (PET) radionuclide production facility" means a facility operating an accelerator for the purpose of producing positron emission tomography radionuclides.

~~((27))~~ (29) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~((or))~~ an authorized radiation safety officer, or an associate radiation safety officer.

~~((28))~~ (30) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive; or

(b) In accordance with the directions of the authorized user for procedures performed under WAC 246-240-151 and 246-240-157.

~~((29))~~ (31) "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

~~((30))~~ (32) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(a) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(b) Is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

~~((31))~~ (33) "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by NRC and the agreement states, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

~~((32))~~ (34) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

~~((33))~~ (35) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

~~((34))~~ (36) "Teletherapy" means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

~~((35))~~ (37) "Temporary job site" means a location where mobile medical services are conducted at other than those fixed ~~((location(s)))~~ locations of use authorized by the license.

~~((36))~~ (38) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

~~((37))~~ (39) "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

~~((38))~~ (40) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

~~((39))~~ (41) "Type of use" means use of radioactive material under WAC 246-240-151, 246-240-157, 246-240-201, 246-240-251, 246-240-301, 246-240-351, or 246-240-501.

~~((40))~~ (42) "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

~~((41))~~ (43) "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in WAC 246-240-060.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-010, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-010, filed 1/18/11, effective 2/18/11. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-010, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 07-14-131, § 246-240-010, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-010, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-240-010, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 92-06-008 (Order 245), § 246-240-010, filed 2/21/92, effective 3/23/92.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-016 License required. (1) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the department, NRC, or an agreement state, or as allowed in subsection (2)(a) or (b) of this section.

(2) A specific license is not needed for an individual who:

(a) Receives, possesses, uses, or transfers radioactive material in accordance with these rules under the supervision of an authorized user under WAC 246-240-057, unless prohibited by license condition; or

(b) Prepares unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user under WAC 246-240-057, unless prohibited by license condition.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-016, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-016, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-019 Application for license, amendment, or renewal.

(1) An application must be signed by the applicant's or licensee's management.

(2) An application for a license for medical use of radioactive material as described in WAC 246-240-151, 246-240-157, 246-240-201, 246-240-251, 246-240-301, 246-240-351, and 246-240-501 must be made by:

(a) Filing the original "Application for Radioactive Material License Medical," with the department that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation safety officers, authorized ((user(s))) users, authorized medical ((physicist(s))) phys-
cists, ophthalmic physicists, and authorized nuclear ((pharmacist(s)))
pharmacists; and

(b) Submitting applicable procedures required by WAC 246-240-360, 246-240-378, 246-240-381, and 246-240-384.

(3) A request for a license amendment or renewal must be made by:

(a) Submitting an original of either to the department:

(i) "Application for Radioactive Material License Medical"; or

(ii) A letter requesting the amendment or renewal with all information required by license application; and

(b) Submitting applicable procedures required by WAC 246-240-360, 246-240-378, 246-240-381, and 246-240-384.

(4) In addition to the requirements in subsections (2) and (3) of this section, an application for a license or amendment for medical use of radioactive material as described in WAC 246-240-501 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in this chapter.

(a) The applicant shall also provide specific information on:

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(b) The applicant or licensee shall also provide any other information requested by the department in its review of the application.

(c) The applicant shall provide identification of and commitment to follow the applicable radiation safety program requirements in WAC 246-240-151 through 246-240-399 of this chapter that are appropriate for the specific medical use under WAC 246-240-501.

(5) An applicant that satisfies the requirements specified in WAC 246-235-090(2) may apply for a Type A specific license of broad scope.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-019, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-022 License amendments. A licensee shall apply for and must receive a license amendment before the licensee:

- (1) Receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but that is not authorized on the licensee's current license issued under this chapter;
- (2) Permits anyone to work as an authorized user, ophthalmic physicist, authorized nuclear pharmacist, or authorized medical physicist under the license, except:
 - (a) For an authorized user, an individual who meets the requirements in WAC 246-240-154, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-278, or 246-240-399;
 - (b) For an authorized nuclear pharmacist, an individual who meets the requirements in WAC 246-240-075 and 246-240-081;
 - (c) For an authorized medical physicist, an individual who meets the requirements in WAC 246-240-072 and 246-240-081; or
 - (d) An individual who is identified as an authorized user, an authorized nuclear pharmacist, (~~((\oplus))~~) authorized medical physicist, or ophthalmic physicist:
 - (i) On an agreement state or NRC license or other equivalent license recognized by the department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy; or
 - (ii) On a permit issued by NRC or an agreement state specific license of broad scope which is licensed to authorize the use of radioactive material in medical use or in the practice of nuclear pharmacy;
 - (iii) On a permit issued by NRC master material licensee that is licensed to authorize the use of radioactive material in medical use or in the practice of nuclear pharmacy; or
 - (iv) By a commercial nuclear pharmacy that has been licensed to authorize nuclear pharmacists.
- (3) Changes radiation safety officers, except as provided in WAC 246-240-051;
- (4) Permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;
- (5) Receives radioactive material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;
- (~~((5))~~) (6) Adds to or changes the areas of use identified in the application or on the license, (~~((except for))~~) including areas used in accordance with either WAC 246-240-151 or 246-240-157 if the change includes the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area. Other areas of use where radioactive material is used only in accordance with either WAC 246-240-151 or 246-240-157 are exempt;
- (~~((6))~~) (7) Changes the address(es) of use identified in the application or on the license; (~~and~~
- (~~((7))~~) (8) Revises procedures required by WAC 246-240-360, 246-240-378, 246-240-381, and 246-240-384, as applicable, where the revision reduces radiation safety; and
- (9) Receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the sealed source and device registry, and is in a quantity and for an isotope authorized by the license.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-022, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-022, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 07-14-131, filed 7/3/07, effective 8/3/07)

WAC 246-240-025 Notifications. (1) A licensee shall notify the department no later than ~~((thirty))~~ 30 days after:

(a) An authorized user, an authorized nuclear pharmacist, a radiation safety officer, an associate radiation safety officer, ophthalmic physicist, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee's mailing address changes;

(c) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in WAC 246-232-050(2);

(d) The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used under either WAC 246-240-151 or 246-240-157 if the change does not include the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area; ~~((or))~~

(e) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in WAC 246-240-022(9). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source; or

(f) The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under WAC 246-240-069 and 246-240-081, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with WAC 246-240-051(3).

(2) The licensee shall send the documents required in this section to the department at P.O. Box 47827, Olympia WA 98504-7827.

[Statutory Authority: RCW 70.98.050. WSR 07-14-131, § 246-240-025, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-025, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-240-025, filed 6/8/98, effective 7/9/98.]

AMENDATORY SECTION (Amending WSR 14-01-077, filed 12/16/13, effective 1/16/14)

WAC 246-240-028 Exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use, issued under WAC 246-235-090, is exempt from the provisions of:

(1) WAC 246-240-019 regarding the need to file an amendment to the license for medical use of radioactive material, as described in WAC 246-240-501;

(2) WAC 246-240-022(2);

(3) WAC 246-240-022(~~(5)~~) (6) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;

(4) WAC 246-240-025 (1)(a) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, or an ophthalmic physicist;

(5) WAC 246-240-025 (1)(d) regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either WAC 246-240-151 or 246-240-157;

(6) WAC 246-240-066.

[Statutory Authority: RCW 70.98.050. WSR 14-01-077, § 246-240-028, filed 12/16/13, effective 1/16/14; WSR 06-05-019, § 246-240-028, filed 2/6/06, effective 3/9/06.]

GENERAL ADMINISTRATIVE REQUIREMENTS

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-051 Authority and responsibilities for the radiation protection program. (1) In addition to the radiation protection program requirements of WAC 246-221-005, a licensee's management shall approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the department;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under WAC 246-240-054;

(2) A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with the written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(3) For up to (~~sixty~~) 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under WAC 246-240-069 and 246-240-081, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer, under subsection (7) of this section, if the licensee takes the actions required in subsections (2), (5), (7), and (8) of this section and notifies the department in accordance with WAC 246-240-025(1).

(4) A licensee may simultaneously appoint more than one temporary radiation safety officer under subsection (3) of this section, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

(5) A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

(6) Licensees that are authorized for two or more different types of use of radioactive material under WAC 246-240-201, 246-240-251, or 246-240-351, shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.

(7) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

- (a) Identify radiation safety problems;
- (b) Initiate, recommend, or provide corrective actions;
- (c) Stop unsafe operations; and
- (d) Verify implementation of corrective actions.

(8) A licensee shall retain a record of actions taken under subsections (1), (2), and (5) of this section in accordance with WAC 246-240-551.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-051, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-051, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 09-06-003, filed 2/18/09, effective 3/21/09)

WAC 246-240-060 Written directives. (1) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 millicuries), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within (~~forty-eight~~) 48 hours of the oral directive.

(2) The written directive must contain the patient or human research subject's name and the following information:

(a) For any administration of quantities greater than 1.11 megabecquerels (30 microcuries) of sodium iodide I-131: The dosage;

(b) For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: The radioactive drug, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: The total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(d) For teletherapy: The total dose, dose per fraction, number of fractions, and treatment site;

(e) For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose; (~~or~~)

(f) For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or

(g) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: The treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: The radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose), and date.

(3) (a) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(b) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within (~~forty-eight~~) 48 hours of the oral revision.

(4) The licensee shall retain a copy of the written directive in accordance with WAC 246-240-557.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-060, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-060, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-063 Procedures for administrations requiring a written directive. (1) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by subsection (1) of this section must address the following items that are applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) Checking both manual and computer-generated dose calculations; ~~((and))~~

(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by WAC 246-240-351 or 246-240-501;

(e) Determining if a medical event, as defined in WAC 246-240-651, has occurred; and

(f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(3) A licensee shall retain a copy of the procedures required under subsection (1) of this section in accordance with WAC 246-240-560.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-063, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-069 Training for radiation safety officer and associate radiation safety officer. Except as provided in WAC 246-240-078, the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer or an individual assigned duties and tasks as an associate radiation safety officer under WAC 246-240-051 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, NRC, or an agreement state, and who meets the requirements of subsection ~~((s))~~ (4) ~~((and (5)))~~ of this section. ~~((Specialty boards whose certification process has been recognized by the department, NRC, or an agreement state will be posted on NRC's web page, at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of ~~((twenty))~~ 20 college credits in physical science;

~~((b))~~ (ii) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

~~((e))~~ (iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have two years of full-time practical training or supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by NRC or an agreement state; or

(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in WAC 246-240-078, 246-240-163 or 246-240-210; and

(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

~~((d) Obtain written attestation signed by a preceptor radiation safety officer that the individual has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or)~~

(2)(a) Has completed a structured educational program consisting of both:

(i) Two hundred hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a department, NRC, or an agreement state license or ~~(license)~~ permit issued by an NRC master material licensee that authorizes similar ~~((type(s) of use(s)))~~ types of uses of radioactive material ~~((involving the following))~~. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a department, NRC, or an agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling radioactive material;

(D) Using administrative controls to avoid mistakes in the administration of radioactive material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control radioactive material; and

(G) Disposing of radioactive material; ~~((e))~~ and

(b) This individual must obtain a written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in (a) of this subsection and subsection (4) of this section, and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; or

(3) (a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, NRC, or an agreement state under WAC 246-240-072 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as radiation safety officer or associate radiation safety officer, and who meets the requirements in subsection (s) (4) ((and (5))) of this section; or

((3)) (b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ((the licensee's license or a medical physicist who has been certified by a specialty board whose certification process has been recognized by the department, NRC or an agreement state under WAC 246-240-072 and)) a department, NRC, or an agreement state license, a permit issued by an NRC master material licensee, a permit issued by the department, NRC, or an agreement state licensee of broad scope, or an NRC master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual ((has)) as the radiation safety officer ((responsibilities; and

(4) Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in subsection (5) of this section, and in subsection (1) (a) and (b), or (c) (i) and (ii) of this section, or subsection (2) (a) or (b) of this section, or subsection (3) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use license; and

(5)) or associate radiation safety officer and meets the requirements in subsection (4) of this section; or

(c) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by an NRC master material licensee. The individual must also meet the requirements in subsection (4) of this section.

(4) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an authorized medical physicist, authorized user, authorized nuclear pharmacist, ((e)) radiation safety

officer, or an associate radiation safety officer, as appropriate, who is authorized for the ~~((type(s)))~~ types of use for which the licensee is seeking approval.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-069, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-069, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-069, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-069, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-072 Training for an authorized medical physicist.

Except as provided in WAC 246-240-078, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, NRC, or an agreement state and who meets the requirements in subsection ~~((s (2) (b) and))~~ (3) of this section. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training ~~((or))~~ and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the department, NRC, or an agreement state; or

(ii) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in WAC 246-240-078, 246-240-278 or 246-240-399;

(c) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) (a) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the ~~((type(s)))~~ types of use ~~((modalities))~~ for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy (photons and electrons with energies greater than

or equal to 1,000,000 electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;
 (ii) Performing decay corrections;
 (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in (~~subsections (1)(a) and (b) and (3), or (2)~~) (a) of this subsection and subsection (3) of this section, and (~~has achieved a level of competency sufficient to function independently~~) is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in WAC 246-240-072, 246-240-078, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status (~~;~~ and).

(3) Has training for the (~~type(s)~~) types of use (~~(in the modalities)~~) for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the (~~type(s)~~) types of use for which the individual is seeking authorization.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-072, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-072, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-072, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-072, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-075 Training for an authorized nuclear pharmacist.

Except as provided in WAC 246-240-078, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the department, NRC, or an agreement state (~~(and who meets the requirements in subsection (2)(b) of this section. (Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.)~~ To be)). The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

- (a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
- (b) Hold a current, active license to practice pharmacy;
- (c) Provide evidence of having acquired at least (~~four thousand~~) 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than (~~two thousand~~) 2,000 hours of the required training and experience; and
- (d) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or
- (2) (a) Has completed (~~two hundred~~) 700 hours in a structured educational program consisting of both:
- (i) (~~Didactic~~) Two hundred hours of classroom and laboratory training in the following areas:
- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Chemistry of radioactive material for medical use; and
- (E) Radiation biology; and
- (ii) Supervised practical experience in a nuclear pharmacy involving:
- (A) Shipping, receiving, and performing related radiation surveys;
- (B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;
- (C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (D) Using administrative controls to avoid medical events in the administration of radioactive material; and
- (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in (~~subsections (1)(a), (b), and (c) or (2)~~) (a) of this (~~section~~) subsection and (~~has achieved a level of competency sufficient to function~~) is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-075, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-075, filed 1/18/11, effective 2/18/11; WSR 06-05-019, § 246-240-075, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-078 Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist. (1)(a) An individual identified on a department, NRC, or an agreement state license; or a permit issued by a department, NRC, or an agreement state broad scope licensee or master material license permit; or by a master material license permittee of broad scope as a radiation safety officer, a teletherapy or medical physicist, ((or)) an authorized medical physicist, a nuclear pharmacist or authorized nuclear pharmacist on ((a department, NRC, or agreement state license, or a permit issued by an agreement state or NRC broad scope licensee or master material license permit, or by a master material license permittee of broad scope)) or before ((October 24, 2006)) January 14, 2019, need not comply with the training requirements of WAC 246-240-069, 246-240-072, or 246-240-075, respectively except the radiation safety officers and authorized medical physicists identified in this subsection must meet the training requirements in WAC 246-240-069(4) or 246-240-072(3), as appropriate, for any material or uses for which they were not authorized prior to this date.

(b) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of WAC 246-240-069 to be identified as a radiation safety officer or as an associate radiation safety officer on a department, NRC, or an agreement state license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(c) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in WAC 246-240-072, for those materials and uses that these individuals performed on or before October 24, 2005.

(d) A radiation safety officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or 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, or an earlier date as noticed by the NRC, need not comply with the training requirements of WAC 246-240-069, 246-240-072 or 246-240-075, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this subsection, qualifies as an authorized nuclear pharmacist or an au-

thorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.

(2) (a) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the department, NRC, or an agreement state, ((or NRC broad scope license, or license)) a permit issued by an NRC master material license, a permit issued by a department, NRC, or an agreement state broad scope licensee, or permit issued by an NRC master material license broad scope permittee on or before ((October 24, 2006)) January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of WAC 246-240-151 ((and)) through 246-240-399.

(b) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the department, NRC, or an agreement state, a permit issued by an NRC master material licensee, a permit issued by the department, NRC, or an agreement state broad scope licensee, or a permit issued in accordance with an NRC master material broad scope license on or before October 24, 2005, need not comply with the training requirements of WAC 246-240-151 through 246-240-399 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(i) For uses authorized under WAC 246-240-151 or 246-240-157, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under WAC 246-240-201, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under WAC 246-240-251 or 246-240-351, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under WAC 246-240-301, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(c) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by

the NRC, need not comply with the training requirements of WAC 246-240-151 through 246-240-399 of this chapter when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this subsection, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(3) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on state of Washington radioactive materials licenses for the same uses for which these individuals are authorized.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-078, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-078, filed 1/18/11, effective 2/18/11; WSR 06-05-019, § 246-240-078, filed 2/6/06, effective 3/9/06.]

GENERAL TECHNICAL REQUIREMENTS

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-104 Calibration of survey instruments. (1) A licensee shall calibrate the survey instruments used to show compliance with this section and WAC 246-240-587 before first use, annually, and following a repair that affects the calibration. A licensee shall:

- (a) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;
- (b) Calibrate two separated readings on each scale or decade that will be used to show compliance; and
- (c) Conspicuously note on the instrument the date of calibration.

(2) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than (~~twenty~~) 20 percent.

(3) A licensee shall retain a record of each survey instrument calibration in accordance with WAC 246-240-566.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-104, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-107 Determination of dosages of unsealed radioactive material for medical use. (1) A licensee shall determine and record the activity of each dosage before medical use.

(2) For a unit dosage, this determination must be made by:

(a) Direct measurement of radioactivity; or

(b) A decay correction, based on the activity or activity concentration determined by:

(i) A manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent NRC or agreement state requirements; or

(ii) An agreement state or NRC licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug protocol accepted by FDA.

(3) For other than unit dosages, this determination must be made by:

(a) Direct measurement of radioactivity;

(b) Combination of measurement of radioactivity and mathematical calculations; or

(c) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer, producer, or preparer licensed under WAC 246-235-100 or equivalent agreement state requirements.

(4) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than (~~twenty~~) 20 percent.

(5) A licensee shall retain a record of the dosage determination required by this section in accordance with WAC 246-240-569.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-107, filed 5/7/13, effective 6/7/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-107, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-107, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-110 Authorization for calibration, transmission, and reference sources. (1) Any person authorized by WAC 246-240-016 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

~~((1))~~ (a) Sealed sources, not exceeding 1.11 gigabecquerels (30 millicuries) each, manufactured and distributed by a person licensed under WAC 246-235-102 or equivalent agreement state or NRC regulations ~~((-))~~;

~~((2))~~ (b) Sealed sources, not exceeding 1.11 gigabecquerels (30 millicuries) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under WAC 246-235-102, or equivalent agreement state or NRC regulations ~~((#))~~, provided the redistributed sealed sources are in

the original packaging and shielding and are accompanied by the manufacturer's approved instructions ~~((-))~~;

~~((3))~~ (c) Any radioactive material with a half-life not longer than ~~((one hundred twenty))~~ 120 days in individual amounts not to exceed 0.56 gigabecquerels (15 millicuries) ~~((-))~~;

~~((4))~~ (d) Any radioactive material with a half-life longer than ~~((one hundred twenty))~~ 120 days in individual amounts not to exceed the smaller of 7.4 megabecquerels (200 microcuries) or ~~((1000))~~ 1,000 times the quantities in Schedule B of WAC 246-232-120 ~~((-))~~; or

~~((5))~~ (e) Technetium-99m in amounts as needed.

(2) Radioactive material in sealed sources authorized by this provision shall not be:

(a) Used for medical use as defined in WAC 246-240-010, except in accordance with the requirements in WAC 246-240-301; or

(b) Combined, such as bundled or aggregated, to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(3) A licensee using calibration, transmission, and reference sources in accordance with the requirements in subsection (1) or (2) of this section need not list these sources on a specific medical use license.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-110, filed 5/7/13, effective 6/7/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-110, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 07-14-131, § 246-240-110, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-110, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-113 Requirements for possession of sealed sources and brachytherapy sources. (1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

(2) A licensee in possession of a sealed source shall:

(a) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(b) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the department, NRC, or an agreement state in the sealed source and device registry.

(3) To satisfy the leak test requirements of this section, the licensee shall ensure the sample is analyzed by such method that the leak test can detect the presence of 185 becquerels (0.005 microcuries) of radioactive material in the sample.

(4) A licensee shall retain leak test records in accordance with WAC 246-240-572(1).

(5) If the leak test reveals the presence of 185 becquerels (0.005 microcurie) or more of removable contamination, the licensee shall:

- (a) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in chapters 246-221 and 246-232 WAC; and
- (b) File a report within five days of the leak test in accordance with WAC 246-240-657.
- (6) A licensee need not perform a leak test on the following sources:
- (a) Sources containing only radioactive material with a half-life of less than (~~thirty~~) 30 days;
- (b) Sources containing only radioactive material as a gas;
- (c) Sources containing 3.7 megabecquerels (100 microcuries) or less of beta- or gamma-emitting material or 0.37 megabecquerel (10 microcuries) or less of alpha-emitting material;
- (d) Seeds of iridium-192 encased in nylon ribbon; and
- (e) Sources stored and not being used. However, the licensee shall test each source for leakage before any use or transfer unless it has been leak tested within six months before the date of use or transfer.
- (7) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory of all the sources in its possession at intervals not to exceed six months. The licensee shall retain each inventory record in accordance with WAC 246-240-572.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-113, filed 5/7/13, effective 6/7/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-113, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-113, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-119 Surveys of ambient radiation exposure rate. (1)

In addition to the surveys required by chapter 246-221 WAC, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

(2) A licensee does not need to perform the surveys required by subsection (1) of this section in (~~an area(s)~~) areas where patients or human research subjects are confined when they cannot be released under WAC 246-240-122.

(3) A licensee shall retain a record of each survey in accordance with WAC 246-240-575.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-119, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-122 Release of individuals containing unsealed radioactive material or implants containing radioactive material. (1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed ((5)) five mSv (0.5 rem).

(2) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed ((±)) one mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed ((±)) one mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

(a) Guidance on the interruption or discontinuation of breast-feeding; and

(b) Information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with WAC 246-240-578(1).

(4) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with WAC 246-240-578(2). NUREG-1556, Vol. 9, "*Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses*," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding ((5)) five mSv (0.5 rem).

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-122, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-128 Decay-in-storage. (1) A licensee may hold radioactive material with a physical half-life of less than ((~~one hundred twenty~~)) 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

(a) Monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

(b) Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

(2) A licensee shall retain a record of each disposal permitted under subsection (1) of this section in accordance with WAC 246-240-584.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-128, filed 2/6/06, effective 3/9/06.]

UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE NOT REQUIRED

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-154 Training for uptake, dilution, and excretion studies. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC 246-240-151 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state (~~and who meets the requirements of subsection (3)(b) of this section. (Specialty boards whose certification process has been recognized by the department, the NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be~~). The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) (~~Meet the requirements in subsection (3)(a)~~) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in subsection (3)(a)(i) through (ii)(F) of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Is an authorized user under WAC 246-240-163 or 246-240-210 or equivalent agreement state or NRC requirements (~~or subsection (3)(a) of this section~~); or

(3) (a) Has completed (~~sixty~~) 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of radioactive material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-154,

246-240-163, or 246-240-210 or equivalent NRC or agreement state requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(b) Has obtained written attestation (~~(, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-154, 246-240-163, or 246-240-210, or equivalent agreement state or NRC requirements,)~~) that the individual has satisfactorily completed the requirements in (a) of this subsection and (~~(has achieved a level of competency sufficient to function)~~) is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under WAC 246-240-151. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-154, 246-240-163, or 246-240-210, or equivalent NRC or agreement state requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-154, 246-240-163, or 246-240-210, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-154, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-154, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-154, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-154, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 09-06-003, filed 2/18/09, effective 3/21/09)

WAC 246-240-160 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations. (1) A licensee may not administer to humans a radiopharmaceutical that contains more than:

(a) ~~((5.55))~~ 0.15 kilobecquerel of molybdenum-99 per ~~((37))~~ megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or

(b) 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection, (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or

(c) 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(2) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration ~~((of the first eluate after receipt of))~~ in each elute from a generator to demonstrate compliance with subsection (1) of this section.

(3) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of strontium-82 and strontium-85 to demonstrate compliance with subsection (1) ~~((a))~~ of this section.

(4) If a licensee is required to measure the molybdenum-99 concentration, or strontium-82 and strontium-85 concentrations the licensee shall retain a record of each measurement in accordance with WAC 246-240-587.

(5) The licensee shall report any measurement that exceeds the limits in subsection (1) of this section at the time of generator elution, in accordance with WAC 246-240-660.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-160, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-160, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-163 Training for imaging and localization studies.

Except as provided in WAC 246-240-078, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC 246-240-157 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state ~~((and who meets the requirements in subsection (3)(b) of this section. (Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~. The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) ~~((Satisfy the requirements in subsection (3)(a))~~ Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subsection (3)(a)(i) through (ii)(G) of this section; and

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(2) Is an authorized user under WAC 246-240-210 and meets the requirements in ~~((WAC 246-240-163))~~ subsection (3) (a) (ii) (G) ~~((and 246-240-210))~~ of this section, or equivalent agreement state or NRC requirements; or

(3) (a) Has completed ~~((seven hundred))~~ 700 hours of training and experience, including a minimum of ~~((eighty))~~ 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

(i) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of radioactive material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and ~~((246-240-163 (3)))~~ (a) (ii) (G) of this subsection, or equivalent agreement state or NRC requirements ~~((, involving))~~. An authorized nuclear pharmacist who meets the requirements in WAC 246-240-075 or 246-240-078 may provide the supervised work experience for (a) (ii) (G) of this subsection. Work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Has obtained written attestation ~~((, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and 246-240-163 (3) (a) (ii) (G) or equivalent agreement state or NRC requirements,))~~ that the individual has satisfactorily completed the requirements in (a) of this subsection and ~~((has achieved a level of competency sufficient to function))~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under WAC 246-240-151 and 246-240-157. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and (a) (ii) (G) of this subsection, or equivalent NRC or agreement state requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the

requirements in WAC 246-240-078, 246-240-163, or 246-240-210 and (a)(ii)(G) of this subsection or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-163, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-163, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-163, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-163, filed 2/6/06, effective 3/9/06.]

UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE REQUIRED

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-201 Use of unsealed radioactive material for which a written directive is required. A licensee may use any unsealed radioactive material identified in WAC 246-240-210 (2)(a)(ii)(G) prepared for medical use and for which a written directive is required that is:

- (1) Obtained from a manufacturer, producer, or preparer licensed under WAC 246-235-100(1) or equivalent agreement state or NRC requirements; or
- (2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in WAC 246-240-163 or 246-240-210, or an individual under the supervision of either as specified in WAC 246-240-057; or
- (3) Obtained from and prepared by an agreement state or NRC licensee for use in research in accordance with an investigational new drug protocol accepted by FDA; or
- (4) Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by FDA.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-201, filed 5/7/13, effective 6/7/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-240-201, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-201, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 14-09-017, filed 4/7/14, effective 5/8/14)

WAC 246-240-210 Training for use of unsealed radioactive material for which a written directive is required. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC 246-240-201 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state and who meets the requirements in subsection (2)(a)(ii)(G) of this section. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes ~~((seven hundred))~~ 700 hours of training and experience as described in subsection (2)(a)(i) through (ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed ~~((by product))~~ radioactive material for which a written directive is required; or

(2) (a) Has completed ~~((seven hundred))~~ 700 hours of training and experience, including a minimum of ~~((two hundred))~~ 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

~~((a))~~ (i) Classroom and laboratory training in the following areas:

~~((i))~~ (A) Radiation physics and instrumentation;

~~((ii))~~ (B) Radiation protection;

~~((iii))~~ (C) Mathematics pertaining to the use and measurement of radioactivity;

~~((iv))~~ (D) Chemistry of radioactive material for medical use; and

~~((v))~~ (E) Radiation biology; and

~~((b))~~ (ii) Work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, or ~~((subsection (1) or (2) of))~~ this section, or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements in this subsection, must also have experience in administering dosages in the same dosage category or categories ~~((i.e., this section))~~ as in (a)(ii)(G) of this subsection as the individual requesting authorized user status. The work experience must involve:

~~((i))~~ (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

~~((ii))~~ (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

~~((iii))~~ (C) Calculating, measuring, and safely preparing patient or human research subject dosages;

~~((iv))~~ (D) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

~~((v))~~ (E) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; ~~(and)~~

(F) (Reserved);

~~((vi))~~ (G) Administering dosages of radioactive drugs to patients or human research subjects ~~(involving)~~ from the three categories in this subsection. Radioactive drugs containing radionuclides in categories not included in this subsection are regulated under WAC 246-240-501. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

~~((A))~~ (I) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for which a written directive is required;

~~((B))~~ (II) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in ~~((b)(vi)(A))~~ (a)(ii)(G)(I) of this subsection;

~~((C))~~ (III) Parenteral administration of any ~~((beta emitter, or a photon-emitting radionuclide with a))~~ radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy less than 150 keV for which a written directive is required;

~~((D))~~ Parenteral administration of any other radionuclide for which a written directive is required;) and

~~((E))~~ (b) Has obtained written attestation that the individual has satisfactorily completed the requirements in (a) of this subsection ~~((1)(a) and (2)(b)(vi) of this section)~~, and ~~((has achieved a level of competency sufficient to function))~~ is able to independently fulfill at radiation safety-related duties as an authorized user for the medical uses authorized under WAC 246-240-201 for which the individual is requesting authorized user status. The written attestation must be ((signed by)) obtained from either:

(i) A preceptor authorized user who meets the requirements in this section, WAC 246-240-078, ~~246-240-210~~, or equivalent NRC or agreement state requirements ~~((The preceptor authorized user, who meets the requirements in this subsection, must also have)), and has experience in administering dosages in the same dosage category or categories ((i.e., this section)) (as in (a)(ii)(G) of this subsection) as the individual requesting authorized user status; or~~

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, ~~246-240-210~~, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be

approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 14-09-017, § 246-240-210, filed 4/7/14, effective 5/8/14; WSR 13-11-021, § 246-240-210, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-210, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-210, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-210, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-213 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). Except as provided in WAC 246-240-078, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3) (a) and (b) of this section and whose certification has been recognized by the department, NRC, or an agreement state. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use/toolkit/spec-board-cert.html>))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page; or

(2) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2) ~~(((b) (vii) (A) and (B)))~~ (a) (ii) (G) (I) or (II), 246-240-216, or equivalent agreement state or NRC requirements; or

(3) (a) Has successfully completed ~~((eighty))~~ 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-213, 246-240-216, or equivalent agreement state or NRC requirements. A supervising authorized user who meets the requirements in WAC 246-240-210(2), must also have experience in administering doses as specified in WAC 246-240-210 (2) ~~(((b) (vii) (A) or (B)))~~

(a) (ii) (G) (I) or (II). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in (a) and (b) of this subsection and (~~has achieved a level of competency sufficient to function~~) is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under WAC 246-240-201. The written attestation must be (~~signed by~~) obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-213, 246-240-216, or equivalent agreement state or NRC requirements (~~. A preceptor authorized user, who meets the requirement in WAC 246-240-210(2), must also have~~), and has experience in administering dosages as specified in WAC 246-240-210 (2) (~~(b)(vii)(A) or (B)~~) (a)(ii)(G)(I) or (II); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-213, 246-240-216, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in WAC 246-240-210 (2) (a)(ii)(G)(I) or (II), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-213, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-213, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-213, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-213, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-216 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). Except as provided in WAC 246-240-078, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive

in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3) (a) and (b) of this section and whose certification has been recognized by the department, NRC, or an agreement state. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page; or

(2) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2) ~~((~~(b) (vii) (B)~~))~~ (a) (ii) (G) (II), or equivalent agreement state or NRC requirements; or

(3) (a) Has successfully completed ~~((~~eighty~~))~~ 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-216, or equivalent agreement state or NRC requirements. A supervising authorized user, who meets the requirements in WAC 246-240-210(2), must also have experience in administering dosages as specified in WAC 246-240-210 (2) ~~((~~(b) (vii) (B)~~))~~ (a) (ii) (G) (II).

The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in (a) and (b) of this subsection and ~~((has achieved a level of competency sufficient to function))~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under WAC 246-240-201. The written attestation must be ((signed by)) obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-216, or equivalent agreement state

or NRC requirements (~~(. A preceptor authorized user, who meets the requirements in WAC 246-240-210(2), must have)~~), and has experience in administering dosages as specified in WAC 246-240-210 (2)

~~((b)(vii)(B))~~ (a)(ii)(G)(II); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-216, or equivalent NRC or agreement state requirements, has experience in administering dosages as specified in WAC 246-240-210 (2)(a)(ii)(G)(II), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-216, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-216, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-216, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-216, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-219 Training for the parenteral administration of unsealed radioactive material requiring a written directive. (1) Except as provided in WAC 246-240-078, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

~~((1))~~ (a) Is an authorized user under WAC 246-240-210 for uses listed in WAC 246-240-210 (2) ~~((b)(vii)(C) or (D))~~ (a)(ii)(G)(III), or equivalent agreement state or NRC requirements; or

~~((2))~~ (b) Is an authorized user under WAC 246-240-278 or 246-240-399, or equivalent agreement state or NRC requirements and who meets the requirements in subsection ~~((4))~~ (2) of this section; or

~~((3))~~ (c) Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under WAC 246-240-278 or 246-240-399, and who meets the requirements in subsection ~~((4))~~ (2) of this section.

~~((4))~~ (2) The physician:

(a) Has successfully completed ~~(eighty)~~ 80 hours of classroom and laboratory training, applicable to parenteral administrations ~~(, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required)~~ listed in WAC 246-240-210

(2)(a)(ii)(G)(III). The training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-219, or equivalent agreement state or NRC requirements, in the parenteral administrations ~~((, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required))~~ listed in WAC 246-240-210 (2) (a) (ii) (G) (III). A supervising authorized user who meets the requirements in WAC 246-240-210, 246-240-219, or equivalent agreement state or NRC requirements, must have experience in administering dosages ~~((as specified in WAC 246-240-210 (2) (b) (vii) (C) or (D)))~~ in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administrations ~~((, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required))~~ as specified in WAC 246-240-210 (2) (a) (ii) (G) (III); and

~~((5))~~ (c) Has obtained written attestation that the individual has satisfactorily completed the requirements in ((subsection (2) or (3)) (a) and (b) of this ((section)) subsection, and ((has achieved a level of competency sufficient to function)) is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be ((signed by)) obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-219, or equivalent agreement state or NRC requirements. A preceptor authorized user, who meets the requirements in WAC 246-240-210, 246-240-219, or equivalent agreement state or NRC requirements, must have experience in administering dosages ((as specified in WAC 246-240-210 (2) (b) (vii) (C) or (D))) in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-210, 246-240-219, or equivalent NRC or agreement state requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of

the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Post-doctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-219, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-219, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-219, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-219, filed 2/6/06, effective 3/9/06.]

MANUAL BRACHYTHERAPY

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-251 Use of sources for manual brachytherapy. A licensee shall use only brachytherapy sources for therapeutic medical uses:

(1) As approved in the sealed source and device registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the sealed source and device registry, but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry; or

(2) In research to deliver therapeutic doses for medical use in accordance with an active investigational device exemption (IDE) application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-251, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-272 ((Decay of)) Strontium-90 sources for ophthalmic treatments. (1) ~~((Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under WAC 246-240-269.~~

~~(2-))~~ Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection (2) of this section are performed by either:

(a) An authorized medical physicist; or

(b) An individual who:

(i) Is identified as an ophthalmic physicist on a specific medical use license issued by a department, NRC, or an agreement state; permit issued by a department, NRC, or an agreement state broad scope medical use licensee; medical use permit issued by an NRC master material licensee; or permit issued by an NRC master material licensee broad scope medical use permittee; and

(ii) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(A) The creation, modification, and completion of written directives;

(B) Procedures for administrations requiring a written directive; and

(C) Performing the calibration measurements of brachytherapy sources as detailed in WAC 246-240-269.

(2) The individuals who are identified in subsection (1) of this section must:

(a) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under WAC 246-240-269; and

(b) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subsection (1) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(3) A licensee shall retain a record of the activity of each strontium-90 source in accordance with WAC 246-240-602.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-272, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-278 Training for use of manual brachytherapy sources. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under WAC 246-240-251 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certifi-

cation process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of ((high and low dose-rate)) manual brachytherapy((; and

~~(c) Obtain written attestation, signed by a preceptor authorized user who meets the requirements in WAC 246-240-278 or equivalent NRC or agreement state requirements, that the individual has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized in WAC 246-240-251)); or~~

(2) (a) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) Two hundred hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-278 or equivalent agreement state or NRC requirements at a medical institution authorized to use radioactive materials under WAC 246-240-251, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of radioactive material;

(F) Using emergency procedures to control radioactive material;

and

(b) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by (a) (ii) of this subsection; and

~~(c) Has obtained written attestation((, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278 or equivalent agreement state or NRC requirements,)) that the individual has satisfactorily completed the requirements in ((sub-section (1) (a) of this section, or)) (a) and (b) of this subsection~~

((and has achieved a level of competency sufficient to function)) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under WAC 246-240-251. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent agreement state or NRC requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-278, or equivalent NRC or agreement state requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-278, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-278, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-278, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-278, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-281 Training for ophthalmic use of strontium-90.

Except as provided in WAC 246-240-078, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under WAC 246-240-278 or equivalent agreement state or NRC requirements; or

(2) (a) Has completed (~~twenty-four~~) 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals.

This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(c) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-278, 246-240-281, or equivalent agreement state or NRC re-

quirements, that the individual has satisfactorily completed the requirements in ~~((subsections (1) and (2)))~~ (a) and (b) of this ~~((section))~~ subsection and ~~((has achieved a level of competency sufficient to function))~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-281, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-281, filed 1/18/11, effective 2/18/11; WSR 06-05-019, § 246-240-281, filed 2/6/06, effective 3/9/06.]

SEALED SOURCES FOR DIAGNOSIS

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-301 Use of sealed sources and medical devices for diagnosis. (1) A licensee shall use only sealed sources that are not in medical devices for diagnostic medical uses ((as)) if the sealed sources are approved in the sealed source and device registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

(2) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the sealed source and device registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the sealed source and device registry but must be used in accordance with the radiation safety conditions and limitations described in the sealed source and device registry.

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active IDE application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-301, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-304 Training for use of sealed sources and medical devices for diagnosis. Except as provided in WAC 246-240-078, the licensee shall require the authorized user of a diagnostic sealed source

((for use in)) a device authorized under WAC 246-240-301 to be a physician, dentist, or podiatrist who:

(1) Is certified by a specialty board whose certification process includes all of the requirements in subsections ~~((2) and))~~ (3) and (4) of this section and whose certification has been recognized by the department, NRC, or an agreement state. ~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.)~~) The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page; or

(2) Is an authorized user for uses listed in WAC 246-240-157 or equivalent NRC or agreement state requirements; or

(3) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

- (d) Radiation biology; and

~~((3))~~ (4) Has completed training in the use of the device for the uses requested.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-304, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-304, filed 2/6/06, effective 3/9/06.]

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-351 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. (1) A licensee shall use sealed sources:

(a) Approved and as provided for in the sealed source and device registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units ~~((for))~~ to deliver therapeutic doses for medical uses ~~((~~

~~(1) As))~~; or

(b) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active IDE application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

(2) A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(a) Approved in the sealed source and device registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the sealed source and device registry, but must be used in accordance with radiation safety conditions and limitations described in the sealed source and device registry; or

~~((2))~~ (b) In research in accordance with an active ((investigational device exemption (IDE))) IDE application accepted by the FDA provided the requirements of WAC 246-240-066(1) are met.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-351, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-354 Surveys of patients and human research subjects treated with a remote afterloader unit. (1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the ~~((source(s)))~~ sources has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of these surveys in accordance with WAC 246-240-593.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-354, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-357 Installation, maintenance, adjustment, and repair. (1) Only a person specifically licensed by the department, NRC, or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the ~~((source(s)))~~ sources shielding, the ~~((source(s)))~~ sources driving unit, or other electronic or mechanical component that could expose the ~~((source(s)))~~ sources, reduce the shielding around the ~~((source(s)))~~ sources, or compromise the radiation safety of the unit or the ~~((source(s)))~~ sources.

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, NRC, or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, NRC, or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed ~~((source(s)))~~ sources contained in the unit.

(4) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy

units, and gamma stereotactic radiosurgery units in accordance with WAC 246-240-605.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-357, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-357, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-360 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. (1) A licensee shall:

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the ~~((source(s)))~~ sources;

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the ~~((source(s)))~~ sources in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by subsection (1)(d) of this section must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of:

(a) The location of the procedures required by subsection (1)(d) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

(4)(a) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(b) A licensee shall provide operational safety instructions, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties((r)). The instructions shall include instruction in:

~~((a))~~ (i) The procedures identified in subsection (1)(d) of this section; and

~~((b))~~ (ii) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(6) A licensee shall retain a record of individuals receiving instruction required by subsection (4) of this section, in accordance with WAC 246-240-590.

(7) A licensee shall retain a copy of the procedures required by subsections (1)(d) and (4)(b) (ii) of this section in accordance with WAC 246-240-608.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-360, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-363 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. (1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(a) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) Cause the ~~((source(s)))~~ sources to be shielded when an entrance door is opened; and

(c) Prevent the ~~((source(s)))~~ sources from being exposed following an interlock interruption until all treatment room entrance doors are closed and the ~~((source(s)))~~ sources on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in subsections (1) through (5) of this section, a licensee shall:

(a) For *medium dose-rate and pulsed dose-rate remote afterloader units*, require:

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user,

who has been trained to remove the source (~~applicator(s)~~) applicators in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For *high dose-rate remote afterloader units*, require:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For *gamma stereotactic radiosurgery units*, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the radiation safety officer, or their designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(a) Remaining in the unshielded position; or

(b) Lodged within the patient following completion of the treatment.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-363, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-366 Dosimetry equipment. (1) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

(a) The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(b) The system must have been calibrated within the previous four years. Eighteen to (~~thirty~~) 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past (~~twenty-four~~) 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and

sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (1) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection (1) of this section.

(3) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with WAC 246-240-611.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-366, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-369 Full calibration measurements on teletherapy units. (1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

- (a) Before the first medical use of the unit; and
- (b) Before medical use under the following conditions:
 - (i) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- (c) At intervals not exceeding one year.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements must include determination of:

- (a) The output within $\pm((3))$ three percent for the range of field sizes and for the distance or range of distances used for medical use;
- (b) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- (d) Timer accuracy and linearity over the range of use;
- (e) On-off error; and
- (f) The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in WAC 246-240-366(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this section may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (5) of this section must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with WAC 246-240-614.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-369, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-372 Full calibration measurements on remote afterloader units. (1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding one calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds (~~seventy-five~~) 75 days; and

(d) At intervals not exceeding one year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements must include, as applicable, determination of:

(a) The output within $\pm((5))$ five percent;

(b) Source positioning accuracy to within $\pm((4))$ one millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Length of the source transfer tubes;

(e) Timer accuracy and linearity over the typical range of use;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in WAC 246-240-366(1) to measure the output.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection (2) of this section, a licensee shall perform an autoradiograph of the (~~source(s)~~) sources to verify inventory and (~~source(s)~~) sources arrangement at intervals not exceeding one calendar quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections (1) through (5) of this section.

(7) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (7) of this section must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with WAC 246-240-614.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-372, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-375 Full calibration measurements on gamma stereotactic radiosurgery units. (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

(a) Before the first medical use of the unit;

(b) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of subsection (1) of this section, full calibration measurements must include determination of:

(a) The output within $\pm((3))$ three percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer accuracy and linearity over the range of use;

(e) On-off error;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in WAC 246-240-366(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this section may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection (1) of this section in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in subsection (2)(a) of this section at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by subsection (1) of this section and physical decay corrections required by subsection (5) of this section must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with WAC 246-240-614.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-375, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-378 Periodic spot-checks for teletherapy units. (1)

A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

- (a) Timer accuracy, and timer linearity over the range of use;
- (b) On-off error;
- (c) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (d) The accuracy of all distance measuring and localization devices used for medical use;
- (e) The output for one typical set of operating conditions measured with the dosimetry system described in WAC 246-240-366(2); and
- (f) The difference between the measurement made in (e) of this subsection and the anticipated output, expressed as a percentage of the anticipated output (~~((i.e.,))~~) such as the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within (~~((fifteen))~~) 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

- (a) Electrical interlocks at each teletherapy room entrance;
- (b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
- (c) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
- (d) Viewing and intercom systems;

(e) Treatment room doors from inside and outside the treatment room; and

(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each spot-check required by subsections (1) and (4) of this section, and a copy of the procedures required by subsection (2) of this section, in accordance with WAC 246-240-617.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-378, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-381 Periodic spot-checks for remote afterloader units. (1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) A licensee shall perform the measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within (~~(fifteen)~~) 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of subsection (1) of this section, spot-checks must, at a minimum, assure proper operation of:

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed (~~(source(s))~~) sources activity in the unit's computer.

(5) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit ex-

cept as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain a record of each check required by subsection (4) of this section and a copy of the procedures required by subsection (2) of this section in accordance with WAC 246-240-620.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-381, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-384 Periodic spot-checks for gamma stereotactic radiosurgery units. (1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

- (a) Monthly;
- (b) Before the first use of the unit on a given day; and
- (c) After each source installation.

(2) A licensee shall:

(a) Perform the measurements required by subsection (1) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(b) Have the authorized medical physicist review the results of each spot-check within (~~(fifteen))~~ 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of subsection (1)(a) of this section, spot-checks must, at a minimum:

(a) Assure proper operation of:

- (i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
- (ii) Helmet microswitches;
- (iii) Emergency timing circuits; and
- (iv) Stereotactic frames and localizing devices (trunnions).

(b) Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in WAC 246-240-366(2);

(ii) The difference between the measurement made in (b)(i) of this subsection and the anticipated output, expressed as a percentage of the anticipated output (~~((i.e.,))~~ such as the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(4) To satisfy the requirements of subsection (1)(b) and (c) of this section, spot-checks must assure proper operation of:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in subsection (3) of this section that is not operating properly as soon as possible.

(6) If the results of the checks required in subsection (4) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain a record of each check required by subsections (3) and (4) of this section and a copy of the procedures required by subsection (2) of this section in accordance with WAC 246-240-623.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-384, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-390 Radiation surveys. (1) In addition to the survey requirement in WAC 246-221-110(1), a person licensed under this chapter shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the ~~((source(s)))~~ sources in the shielded position do not exceed the levels stated in the sealed source and device registry.

(2) The licensee shall make the survey required by subsection (1) of this section at installation of a new source and following repairs to the ~~((source(s)))~~ sources shielding, the ~~((source(s)))~~ sources driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the ~~((source(s)))~~ sources, or compromise the radiation safety of the unit or the ~~((source(s)))~~ sources.

(3) A licensee shall retain a record of the radiation surveys required by subsection (1) of this section in accordance with WAC 246-240-629.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-390, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-393 (~~(Five-year inspection)~~) Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units. (1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement ~~((or at intervals not to exceed five years, whichever comes first,))~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and

shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the department, NRC, or an agreement state.

(3) A licensee shall keep a record of the inspection and servicing in accordance with WAC 246-240-632.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-393, filed 5/7/13, effective 6/7/13; WSR 06-05-019, § 246-240-393, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-399 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of a sealed source for a use authorized under WAC 246-240-351 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC, or an agreement state and meets the requirements in subsection (3) of this section. (~~((Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.) To be))~~ The names of board certifications that have been recognized by the department, NRC, or an agreement state are posted on the NRC's medical uses licensee toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the (~~Committee on Postgraduate~~) Council of Postdoctoral Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(2) (a) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) Two hundred hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) Five hundred hours of work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, 246-240-399, or equivalent agreement state or NRC requirements, at a

medical institution(~~(r)~~) that is authorized to use radioactive materials in WAC 246-240-351 involving:

- (A) Reviewing full calibration measurements and periodic spot-checks;
 - (B) Preparing treatment plans and calculating treatment doses and times;
 - (C) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - (E) Checking and using survey meters; and
 - (F) Selecting the proper dose and how it is to be administered;
- and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in WAC 246-240-078, 246-240-399 or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the (~~Committee~~) Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by (a) (ii) of this subsection; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in (~~subsection (1)~~) (a) and (b) of this subsection, and subsection (3) of this section(~~(r or (a) and (b)~~, and (d) of this subsection and has achieved a level of competency sufficient to function)) and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be (~~signed by~~) obtained from either:

(i) A preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-399, or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status(~~(r and~~

~~(d)~~); or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in WAC 246-240-078, 246-240-399, or equivalent NRC or agreement state requirements, for the types of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in (a) and (b) of this subsection.

(3) Has received training in device operation, safety procedures, and clinical use for the (~~(type(s))~~) types of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for

the (~~(type(s))~~) types of use for which the individual is seeking authorization.

[Statutory Authority: RCW 70.98.050. WSR 13-11-021, § 246-240-399, filed 5/7/13, effective 6/7/13; WSR 11-03-068, § 246-240-399, filed 1/18/11, effective 2/18/11; WSR 07-14-131, § 246-240-399, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-240-399, filed 2/6/06, effective 3/9/06.]

OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL

RECORDS

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-551 Records of authority and responsibilities for radiation protection programs. (1) A licensee shall retain a record of actions taken by the licensee's management in accordance with WAC 246-240-051(1) for five years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a copy of both authority, duties, and responsibilities of the radiation safety officer as required by WAC 246-240-051(5), and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as required by WAC 246-240-051(2), for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

(3) For each associate radiation safety officer appointed under WAC 246-240-051(2), the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-551, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-578 Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material. (1) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with WAC 246-240-122, if the total effective dose equivalent is calculated by:

(a) Using the retained activity rather than the activity administered;

(b) Using an occupancy factor less than 0.25 at ((±)) one meter;

(c) Using the biological or effective half-life; or

(d) Considering the shielding by tissue.

(2) A licensee shall retain a record that the instructions required by WAC 246-240-122(2) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding ((5)) five mSv (0.5 rem).

(3) The records required by subsections (1) and (2) of this section must be retained for three years after the date of release of the individual.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-578, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-590 Records of safety instruction. A licensee shall maintain a record of safety instructions required by WAC 246-240-204, 246-240-263, and the operational and safety instructions required by WAC 246-240-360 for three years. The record must include a list of the topics covered, the date of the instruction, the ((name(s-))) names of the ((attendee(s-))) attendees, and the ((name(s-))) names of the ((individual(s-))) individuals who provided the instruction.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-590, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by WAC 246-240-357 for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and ((name(s-))) names of the ((individual(s-))) individuals who performed the work.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-605, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-614 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. (1) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by WAC 246-240-369, 246-240-372, and 246-240-375 for three years.

(2) The record must include:

- (a) The date of the calibration;
- (b) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery ~~((unit(s)))~~ units, the ~~((source(s)))~~ sources, and the instruments used to calibrate the ~~((unit(s)))~~ units;
- (c) The results and an assessment of the full calibrations;
- (d) The results of the autoradiograph required for low dose-rate remote afterloader units; and
- (e) The signature of the authorized medical physicist who performed the full calibration.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-614, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-632 Records of ~~((five-year inspection))~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units. (1) A licensee shall maintain a record of the ~~((five-year inspections))~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by WAC 246-240-393 for the duration of use of the unit.

(2) The record must contain:

- (a) The inspector's radioactive materials license number;
- (b) The date of inspection;
- (c) The manufacturer's name and model number and serial number of both the treatment unit and source;
- (d) A list of components inspected and serviced, and the type of service; and
- (e) The signature of the inspector.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-632, filed 2/6/06, effective 3/9/06.]

REPORTS

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-651 Report and notification of a medical event. (1)

A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which:

(a) The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

~~((a))~~ (i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv ~~((5))~~ five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

~~((i))~~ (A) The total dose delivered differs from the prescribed dose by ~~((twenty))~~ 20 percent or more;

~~((ii))~~ (B) The total dosage delivered differs from the prescribed dosage by ~~((twenty))~~ 20 percent or more or falls outside the prescribed dosage range; or

~~((iii))~~ (C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by ~~((fifty))~~ 50 percent or more.

~~((b))~~ (ii) A dose that exceeds 0.05 Sv ~~((5))~~ five rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

~~((i))~~ (A) An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

~~((ii))~~ (B) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~((iii))~~ (C) An administration of a dose or dosage to the wrong individual or human research subject;

~~((iv))~~ (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

~~((v))~~ (E) A leaking sealed source.

~~((e))~~ (iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(A) 0.5 Sv (50 rem) ~~((to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)))~~ or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(B) Fifty percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(b) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(A) The wrong radionuclide;

(B) The wrong individual or human research subject;

(C) Sealed sources implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or

(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify by telephone (360-236-3300) the department no later than the next calendar day after discovery of the medical event.

(4) By an appropriate method listed in WAC 246-221-250, the licensee shall submit a written report to the department at P.O. Box 47827, Olympia WA 98504-7827 within (~~(fifteen)~~) 15 days after discovery of the medical event.

(a) The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the (~~(individual(s))~~) individuals who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than (~~(twenty-four)~~) 24 hours after its discovery, unless the referring physician personally informs the licensee either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within (~~(twenty-four)~~) 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements

of this (~~section~~) subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(7) A licensee shall:

(a) Annotate a copy of the report provided to the department with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social Security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than (~~fifteen~~) 15 days after the discovery of the event.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-651, filed 2/6/06, effective 3/9/06.]

AMENDATORY SECTION (Amending WSR 06-05-019, filed 2/6/06, effective 3/9/06)

WAC 246-240-654 Report and notification of a dose to an embryo/fetus or a nursing child. (1) A licensee shall report to the department at P.O. Box 47827, Olympia WA 98504-7827, (phone 360-236-3300), any dose to an embryo/fetus that is greater than 50 mSv (~~(5)~~) five rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) Is greater than 50 mSv (~~(5)~~) five rem) total effective dose equivalent; or

(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (1) or (2) of this section.

(4) By an appropriate method listed in WAC 246-221-250, the licensee shall submit a written report to the department within (~~fifteen~~) 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subsection (1) or (2) of this section.

(a) The written report must include:

(i) The licensee's name;

- (ii) The name of the prescribing physician;
- (iii) A brief description of the event;
- (iv) Why the event occurred;
- (v) The effect, if any, on the embryo/fetus or the nursing child;
- (vi) What actions, if any, have been taken or are planned to prevent recurrence; and
- (vii) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than (~~twenty-four~~) 24 hours after discovery of an event that would require reporting under subsection (1) or (2) of this section, unless the referring physician personally informs the licensee either that they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within (~~twenty-four~~) 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide a written description if requested.

(6) A licensee shall:

(a) Annotate a copy of the report provided to the department with the:

(i) Name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) Social Security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than (~~fifteen~~) 15 days after the discovery of the event.

[Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-240-654, filed 2/6/06, effective 3/9/06.]

NEW SECTION

WAC 246-240-660 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations. (1) The licensee shall notify by telephone the department and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in

WAC 246-240-160(1) at the time of generator elution. The telephone report to the department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(2) By an appropriate method listed in WAC 246-221-250, the licensee shall submit a written report to the department at P.O. Box 47827, Olympia WA 98504-7827 within 30 days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subsection (1) of this section.

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