Chapter 246-233 WAC

RADIOACTIVE MATERIALS—GENERAL LICENSES

WAC	
246-233-001	Purpose and scope.
246-233-005	Ownership of radioactive material.
246-233-010	General licenses—Source material.
246-233-012	General license for certain items and self-luminous
	products containing radium-226.
246-233-015	Certain devices and equipment.
246-233-020	General license—Certain measuring, gauging or con-
	trolling devices.
246-233-025	General license—Luminous safety devices for aircraft.
246-233-030	General license—Ice detection devices.
246-233-035	General license—Calibration and reference sources.
246-233-040	General license for use of radioactive material for cer-
	tain <i>in vitro</i> clinical or laboratory testing.

WAC 246-233-001 Purpose and scope. This chapter establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material. Chapter 246-232 WAC also contains provisions applicable to the general licenses established in this part.

[Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-001, filed 1/30/04, effective 3/1/04. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-233-001, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-233-001, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-010, filed 11/30/79, effective 1/1/80. Formerly chapter 402-20 WAC.]

WAC 246-233-005 Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

[Statutory Authority: RCW 70.98.050. 04-04-055, \$ 246-233-005, filed 1/30/04, effective 3/1/04.]

WAC 246-233-010 General licenses—Source mate-

- **rial.** (1) A general license is hereby issued authorizing use, possession, and transfer of not more than fifteen pounds of source material at any one time by persons in the following categories:
- (a) Pharmacists using the source material solely for the preparation of medicinal compounds;
- (b) Physicians using the source material for medicinal purposes;
- (c) Persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;
- (d) Commercial and industrial firms, and research, educational, and medical institutions, and state and local government agencies for research, development, educational, operational, or commercial purposes: And provided, That no such person shall, pursuant to this general license, receive more than a total of one hundred fifty pounds of source material in any one calendar year.

- (2) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in subsection (1) of this section are exempt from the provisions of chapters 246-221 and 246-222 WAC to the extent that such receipt, possession, use, or transfer is within the terms of such general license: Provided, however, That this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to chapter 246-235 WAC.
- (3) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.
 - (4) Depleted uranium in industrial products and devices.
- (a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs (4)(b), (c), (d), and (e) of this section, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
- (b) The general license in paragraph (4)(a) of this section applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to WAC 246-235-091 or in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the United States Nuclear Regulatory Commission or an agreement state.
- (c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph (4)(a) of this section shall file department form RHF-20 "Registration certificate Use of depleted uranium under general license," with the department. The form shall be submitted within thirty days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on department form RHF-20 the following information and such other information as may be required by that form:
 - (A) Name and address of the registrant;
- (B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph (4)(a) of this section and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
- (C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in item (4)(c)(i)(B) of this section.
- (ii) The registrant possessing or using depleted uranium under the general license established by paragraph (4)(a) of this section shall report in writing to the department any

(2/18/09) [Ch. 246-233 WAC—p. 1]

changes in information previously furnished on the "Registration certificate - Use of depleted uranium under general license." The report shall be submitted within thirty days after the effective date of such change.

- (d) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph (4)(a) of this section:
- (i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.
 - (ii) Shall not abandon such depleted uranium.
- (iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provision of chapter 246-232 WAC. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph (4)(a) of this section the transferor shall furnish the transferee a copy of this regulation and a copy of department form RHF-20.

In the case where the transferee receives the depleted uranium pursuant to a general license contained in the United States Nuclear Regulatory Commission's or agreement state's regulation equivalent to paragraph (4)(a) of this section the transferor shall furnish the transferee a copy of this regulation and a copy of department form RHF-20 accompanied by a note explaining that use of the product or device is regulated by the United States Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in this regulation.

- (iv) Shall maintain and make available to the department upon request the name and address of the person receiving the depleted uranium pursuant to such transfer.
- (v) Shall not export such depleted uranium except in accordance with a license issued by the United States Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
- (e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph (4)(a) of this section is exempt from the requirements of chapters 246-221 and 246-222 WAC of these regulations with respect to the depleted uranium covered by that general license.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-233-010, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-233-010, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-233-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-21-030, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-030, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-030.]

WAC 246-233-012 General license for certain items and self-luminous products containing radium-226. (1) A general license shall be issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of subsections (2), (3), and (4) of this section, radium-226 contained in:

(a) Antiquities originally intended for use by the general public. For the purposes of this subsection, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon

generators, refrigerator cards, radium bath salts, and healing pads.

- (b) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.
- (c) Luminous items installed in air, marine, or land vehicles.
- (d) All other luminous products, provided that no more than one hundred items are used or stored at the same location at any one time.
- (e) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this subsection, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the department of health.
- (2) Persons who acquire, receive, possess, use, or transfer radioactive materials under the general license issued in subsection (1) of this section are exempt from the provisions of chapters 246-221 and 246-222 WAC to the extent that such receipt, possession, use, or transfer is within the terms of such general license. This exemption shall not apply to any person who is also in possession of radioactive materials under a specific license issued under chapter 246-235 WAC.
- (3) Any person who acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license in subsection (1) of this section:
- (a) Shall notify the department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the department within thirty days
- (b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be transferred or disposed of in accordance with chapter 246-232 WAC, or as otherwise approved by the department.
- (c) Shall not export products containing radium-226 except in accordance with chapter 246-231 WAC.
- (d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under chapter 246-235 WAC, or equivalent regulations of an agreement state, or as otherwise approved by the NRC.
- (e) Shall respond to written requests from the department to provide information relating to the general license within thirty calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing a written justification for the request.

[Ch. 246-233 WAC—p. 2] (2/18/09)

(4) The general license in subsection (1) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-012, filed 2/18/09, effective 3/21/09.]

- WAC 246-233-015 Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, chapters 246-232, 246-221** and 246-222 WAC.
- (1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerels (500 microcuries) of Polonium-210 per device.
- (2) *Ion generating tube.* Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerels (500 microcuries) of Polonium-210 per device or a total of not more than 18.5 megabecquerels (50 millicuries) of Hydrogen-3 (tritium) per device.
 - ** Attention is directed particularly to the provisions of chapter 246-221 WAC which relate to the labeling of containers.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-015, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-015, filed 1/30/04, effective 3/1/04.]

- WAC 246-233-020 General license—Certain measuring, gauging or controlling devices. (1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of subsections (2), (3), and (4) of this section, radioactive material excluding special nuclear material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- (2) The general license in subsection (1) of this section applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to WAC 246-235-093 or in accordance with the Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution or transfer of devices to persons generally licensed by the United States Nuclear Regulatory Commission, an agreement state or licensing state**. The devices shall have been received from one of the specific licensees described in this subsection or through a transfer made under subsection (3)(h) of this section.

**Note: Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 CFR Part 179.

- (3) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in subsection (1) of this section:
- (a) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- (b) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however:
- (i) Devices containing only krypton need not be tested for leakage of radioactive material; and
- (ii) Devices containing only tritium or not more than 3.7 megabecquerels (100 microcuries) of other beta and/or gamma emitting material or 370 kilobecquerels (10 microcuries) of alpha emitting material need not be tested for any purpose. Devices held in storage in the original shipping container prior to initial installation need not be tested until immediately prior to use;
- (c) Shall assure that the tests required by (b) of this subsection and other testing, installing, servicing, and removing from installation involving the radioactive materials, its shielding or containment, are performed:
- (i) In accordance with the instructions provided by the labels; or
- (ii) By a person holding a specific license from the department or from the United States Nuclear Regulatory Commission or from any agreement state or from a licensing state to perform such activities;
- (d) Shall maintain records showing compliance with the requirements of (b) and (c) of this subsection. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removing from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (b) of this subsection shall be maintained for three years after the next required leak test is performed or the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by (b) of this subsection shall be maintained for three years after the next required test of the on/off mechanism and indicator is performed or the sealed source is transferred or disposed. Records of other testing, installation, servicing, and removal from installation required by (c) of this subsection shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed;
- (e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 185 becquerels (0.005 microcuries) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the department, the United States Nuclear

(2/18/09) [Ch. 246-233 WAC—p. 3]

Regulatory Commission, or from an agreement state or a licensing state to repair such devices, or disposed by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within thirty days, furnish to the department a written report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerels (0.005 microcuries) or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use (see WAC 246-246-020);

- (f) Shall not abandon the device containing radioactive material;
- (g) Except as provided in (h) of this subsection, shall transfer or dispose the device containing radioactive material only by transfer to a person holding a specific license of the department, the United States Nuclear Regulatory Commission, or an agreement state, or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address, and license number of the person receiving the device, and the date of transfer. Prior written approval from the department is required before transferring the device to any other specific licensee not specifically identified in this subsection;
- (h) Shall transfer the device to another general licensee only:
- (i) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this section, a copy of WAC 246-221-240, 246-221-250, 246-232-050, and 246-232-060, and any safety documents identified in the label of the device and within thirty days of the transfer, report to the department the manufacturer's (or transferor's) name, model number, and serial number of device transferred, the transferee's name and mailing address for the location of use, and the name, title, and phone number of the responsible individual identified by the transferee in accordance with (j) of this subsection to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or
- (ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee:
- (i) Shall comply with the provisions of WAC 246-221-240 and 246-221-250 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of chapters 246-221 and 246-222 WAC;
- (j) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;
- (k)(i) Shall register, in accordance with (k)(ii) and (iii) of this subsection, devices containing at least 370 megabecquerels (10 millicuries) of Cesium-137, 3.7 megabecquerels (0.1

- millicuries) of Strontium-90, 37 megabecquerels (1 millicurie) of Cobalt-60, or 37 megabecquerels (1 millicurie) of Americium-241, 3.7 megabecquerels (0.1 millicurie) of Radium-226, or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under (k)(iii)(D) of this subsection, represents a separate general licensee and requires a separate registration and fee;
- (ii) If in possession of a device meeting the criteria of (k)(i) of this subsection, shall register these devices annually with the department and shall pay the fee required by WAC 246-254-090. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the department. The registration information must be submitted to the department within thirty days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of (k)(i) of this subsection is subject to the bankruptcy notification requirement in WAC 246-232-050;
- (iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the department:
 - (A) Name and mailing address of the general licensee;
- (B) Information about each device: The manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label);
- (C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under (j) of this subsection;
- (D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;
- (E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;
- (F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license;
- (iv) Persons generally licensed by the U.S. Nuclear Regulatory Commission, or an agreement state with respect to devices meeting the criteria in (k)(i) of this subsection are not subject to registration requirements if the devices are used in areas subject to Washington state jurisdiction for a period less than one hundred eighty days in any calendar year. The department will not request registration information from such licensees:
- (l) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the department within thirty days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;
- (m) Shall not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by (b) of this subsection need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and

[Ch. 246-233 WAC—p. 4] (2/18/09)

have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

- (4) The general license in subsection (1) of this section does not authorize the manufacture, import or export of devices containing radioactive material.
- (5) The general license provided in this subsection is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-221-240, 246-221-250, 246-232-050, 246-232-060, 246-232-070, 246-232-080, and 246-232-090.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-020, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-020, filed 1/30/04, effective 3/1/04; 98-13-037, § 246-233-020, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-233-020, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-233-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-21-050, filed 12/11/86; 83-19-050 (Order 2026), § 402-21-050, filed 9/16/83. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-21-050, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-050, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-040.]

WAC 246-233-025 General license—Luminous safety devices for aircraft. (1) A general license is hereby issued to own, receive, acquire, possess and use tritium or Promethium-147 contained in luminous safety devices for use in aircraft, provided:

- (a) Each device contains not more than 370 gigabecquerels (10 curies) of tritium or 11.1 gigabecquerels (300 millicuries) of Promethium-147; and
- (b) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.
- (2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this subsection are exempt from the requirements of chapters 246-221 and 246-222 WAC except that they shall comply with the provisions of WAC 246-221-240 and 246-221-250.
- (3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or Promethium-147.
- (4) This general license does not authorize the ownership, receipt, acquisition, possession or use of Promethium-147 contained in instrument dials.
- (5) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-025, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-025, filed 1/30/04, effective 3/1/04.]

WAC 246-233-030 General license—Ice detection devices. (1) A general license is hereby issued to own, receive, acquire, possess, use and transfer Strontium-90 contained in ice detection devices, provided each device contains not more than 185 megabecquerels (50 microcuries) of Strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.

- (2) Persons who own, receive, acquire, possess, use or transfer Strontium-90 contained in ice detection devices pursuant to the general license in (a) of this subsection:
- (a) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of these regulations;
- (b) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
- (c) Are exempt from the requirements of chapters 246-221 and 246-222 WAC except that such persons shall comply with the provisions of WAC 246-221-170, 246-221-240, and 246-221-250.
- (3) This general license does not authorize the manufacture, assembly, disassembly or repair of Strontium-90 sources in ice detection devices.
- (4) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-030, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-030, filed 1/30/04, effective 3/1/04.]

WAC 246-233-035 General license—Calibration and reference sources. (1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of subsections (4) and (5) of this section, Americium-241 in the form of calibration or reference sources:

- (a) Any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material; or
- (b) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.

(2/18/09) [Ch. 246-233 WAC—p. 5]

- (2) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections (4) and (5) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.
- (3) A general license is hereby issued to own, receive, possess, use and transfer Radium-226 in the form of calibration or reference sources in accordance with the provisions of subsections (4) and (5) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.
- (4) The general licenses in subsections (1), (2) and (3) of this section apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department or any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the United States Nuclear Regulatory Commission.
- (5) The general licenses provided in subsections (1), (2) and (3) of this section are subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, 246-232-090, chapters 246-221 and 246-222 WAC.

In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

- (a) Shall not possess at any one time, at any one location of storage or use, more than 185 kilobecquerels (5 microcuries) of Americium-241 and 185 kilobecquerels (5 microcuries) of plutonium and 185 kilobecquerels (5 microcuries) of Radium-226 in such sources;
- (b) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

(i)

The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

Name of manufacturer or importer

*Note: Showing only the name of the appropriate material.

(ii)

The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the regulations of any licensing state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

Name of manufacturer or importer

- (c) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the United States Nuclear Regulatory Commission, or an agreement state or licensing state to receive the source:
- (d) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain Americium-241, plutonium, or Radium-226/Radon-222 which might otherwise escape during storage; and
- (e) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources
- (6) These general licenses do not authorize the manufacture of calibration or reference sources containing Americium-241, plutonium, or Radium-226.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-035, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-035, filed 1/30/04, effective 3/1/04.]

WAC 246-233-040 General license for use of radioactive material for certain *in vitro* clinical or laboratory testing.* (1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (2), (3), (4), (5), and (6) of this section the following radioactive materials in prepackaged units:

- (a) Iodine-125, in units not exceeding 370 kilobecquerels (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (b) Iodine-131, in units not exceeding 370 kilobecquerels (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (c) Carbon-14, in units not exceeding 370 kilobecquerels (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (d) Hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerels (50 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (e) Iron-59, in units not exceeding 740 kilobecquerels (20 microcuries) each for use in *in vitro* clinical or laboratory

[Ch. 246-233 WAC—p. 6] (2/18/09)

tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

- (f) Cobalt-57, in units not exceeding 370 kilobecquerels (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (g) Selenium-75, in units not to exceed 370 kilobecquerels (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
- (h) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of Iodine-129 and 185 becquerels (0.005 microcurie) of Americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

*Note: The new drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

- (2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (1) of this section until that person has received a validated copy of department Form RHF-15 "Certificate *in vitro* testing with radioactive material under general license." Annual validation requires resubmittal of revised department Form RHF-15 and submittal of the annual fee to the department. The physician, veterinarian, clinical laboratory or hospital shall furnish on department Form RHF-15 the following information and such other information as may be required by that form:
- (a) Name and address of the physician, veterinarian, clinical laboratory or hospital;
 - (b) The location of use; and
- (c) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive material as authorized under the general license in subsection (1) of this section and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- (3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subsection (1) of this section shall comply with the following:
- (a) The general licensee shall not possess at any one time, pursuant to the general license in subsection (1) of this section at any one location of storage or use, a total amount of Iodine-125, Iodine-131, Selenium-75, Iron-59, and/or Cobalt-57 in excess of 7.4 megabecquerels (200 microcuries).
- (b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- (c) The general licensee shall use the radioactive material only for the uses authorized by subsection (1) of this section.

- (d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
- (e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subsection (1)(h) of this section as required by WAC 246-221-170.
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subsection (1) of this section:
- (a) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to WAC 246-235-097 or in accordance with the provisions of a specific license issued by the United States Nuclear Regulatory Commission, or any agreement state or licensing state which authorizes the manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (tritium), Iron-59, Selenium-75, Cobalt-57, or Mock Iodine-125 to persons generally licensed under this subsection or its equivalent; and
- (b) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (1) of this section shall report in writing to the department, any changes in the information previously furnished in the "Certificate - *in vitro* testing with radioactive material under general license," department Form

(2/18/09) [Ch. 246-233 WAC—p. 7]

RHF-15. The report shall be furnished within thirty days after the effective date of such change.

(6) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-090 and 246-220-100. In addition, any person using radioactive material pursuant to the general license of subsection (1) of this section is exempt from the requirements of chapters 246-221 and 246-222 WAC with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in subsection (1)(h) of this section shall comply with the provisions of WAC 246-221-170, 246-221-240, and 246-221-250 and of these regulations.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-040, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-040, filed 1/30/04, effective 3/1/04.]

[Ch. 246-233 WAC—p. 8] (2/18/09)