# RULE-MAKING ORDER

**CR-103P (May 2009)**
**(Implements RCW 34.05.360)**

Agency: Department of Health
.

**Permanent Rule Only**

**Effective date of rule:**
**Permanent Rules**
☒ 31 days after filing.
☐ **Other (specify)** **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

**Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?**
☐ Yes ☒ No If Yes, explain:

**Purpose:** **General Licensing, chapter 246-232 WAC, radioactive material-licensing applicability, chapter 246-233 WAC, radioactive materials-general licenses, and chapter 246-235 WAC, radioactive materials-specific licenses. The department is adopting federal rule changes to make Washington State rules consistent with the federal Nuclear Regulatory Commission's (NRC) rules and make editorial changes.**

**Citation of existing rules affected by this order:**
Repealed: WAC 246-232-013
Amended: See attached "Amended sections"
Suspended: None

**Statutory authority for adoption:** 70.98.050

**Other authority :**

**PERMANENT RULE (Including Expedited Rule Making)**
Adopted under notice filed as WSR 13-18-049 on 08/30/2013 (date).
Describe any changes other than editing from proposed to adopted version:

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: phone
Address: fax
e-mail

**Date adopted:** 11/21/2013

**NAME (TYPE OR PRINT)**
Jessica Todorovich for John Wiesman, DrPH, MPH

**SIGNATURE**

**TITLE**
Deputy Secretary for Secretary of Health

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 22, 2013
TIME: 2:01 PM

WSR 13-24-025

**(COMPLETE REVERSE SIDE)**

**Note: If any category is left blank, it will be calculated as zero. No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.**

**The number of sections adopted in order to comply with:**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Federal statute:** | New | 0 | Amended | 0 | Repealed | 0 |
| **Federal rules or standards:** | New | 0 | Amended | 37 | Repealed | 1 |
| **Recently enacted state statutes:** | New | 0 | Amended | 0 | Repealed | 0 |

**The number of sections adopted at the request of a nongovernmental entity:**

| | | | | | |
|---|---|---|---|---|---|
| New | 0 | Amended | 0 | Repealed | 0 |

**The number of sections adopted in the agency's own initiative:**

| | | | | | |
|---|---|---|---|---|---|
| New | 0 | Amended | 0 | Repealed | 0 |

**The number of sections adopted in order to clarify, streamline, or reform agency procedures:**

| | | | | | |
|---|---|---|---|---|---|
| New | 0 | Amended | 0 | Repealed | 0 |

**The number of sections adopted using:**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Negotiated rule making:** | New | 0 | Amended | 0 | Repealed | 0 |
| **Pilot rule making:** | New | 0 | Amended | 0 | Repealed | 0 |
| **Other alternative rule making:** | New | 0 | Amended | 37 | Repealed | 1 |

**Attached Amended Sections for General Licensing, chapter 246-232 WAC 246-232 WAC, radioactive material-licensing applicability, chapter 246-233 WAC, radioactive materials-general licenses, and chapter 246-235 WAC, radioactive materials-specific licenses.**

**Chapter 246-232**

-001
-006
-007
-008
-009
-010
-011
-012
-014
-020
-040
-050
-060
-080
-130

**Chapter 246-233**

-001
-005
-010
-012
-015
-020
-025
-030
-035
-040

**Chapter 246-235**

-010
-075
-080
-090
-091
-093
-097
-100
-102
-103
-105
-130

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

**WAC 246-235-010 Filing application for specific licenses.** (1) Applications for specific licenses shall be filed on department 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 shall 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.

(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) 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) Identify the source or device by manufacturer and model number; or

(b) Be registered with the ((~~U.S. Nuclear Regulatory Commission~~)) NRC under 10 C.F.R. 32.210; or

(c) For sources not registered with the ((~~U.S.~~)) NRC, provide 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, relevant operational safety history, and the results of the most recent leak test.

(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.

AMENDATORY SECTION (Amending WSR 07-03-049, filed 1/12/07, effective 2/12/07)

**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 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 ((~~isotopes~~)) 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 ((~~isotope~~)) 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 shall contain:

(a) A cost estimate for decommissioning facilities impacted by the activities authorized in the specific license.

(b) A description of the method of assuring funds for decommissioning.

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

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

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

(3) Each cost estimate for decommissioning shall include:

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

(b) Anticipated labor, equipment and material costs.

(c) Anticipated waste volume.

(d) Anticipated packaging, transportation and waste disposal costs.

(e) An assessment of costs associated with an accident involving licensed material.

(4) Each applicant shall submit a certification that financial assurance for decommissioning shall be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit of sufficient funds to pay decommissioning costs. Funds shall 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.

(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 shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless ninety 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 shall also require that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the li-

censee fails to provide a replacement acceptable to the department within thirty days after receipt of notification of cancellation.

(ii) The surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall 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 shall 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 shall 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 ((~~U.S. Nuclear Regulatory Commission~~)) NRC guidance.

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

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

(c) 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 shall be submitted to the department before receipt of licensed material.

(d) Licensees shall implement the financial assurance requirements within thirty days of receiving department approval of the initial or updated decommissioning funding plan. Licensees shall submit copies of the financial surety within thirty 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 re-

cords 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. Information the department considers important to decommissioning consists of:

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. 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 shall include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(b) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used ((~~and/~~))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.

(c) 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 days, a list contained in a single document and updated every two years, of the following:

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

(ii) All areas outside of restricted areas that require documentation under (a) of this subsection;

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under WAC 246-221-230 (8)(a); and

(iv) 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 decommissioning 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.

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

**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 ((~~shall~~)) must test for leakage or contamination each sealed source containing radioactive material, other than Hydrogen-3, with a half-life greater than thirty days in any form other than gas ((~~and/or contamination~~)) 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 ((~~shall~~)) 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 ((~~and/~~))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 ((~~shall~~)) must be capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample. The test sample shall 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 ((~~shall~~)) 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 ((~~shall~~)) must immediately withdraw the sealed source from use and shall 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 describing the equipment involved, the test results, and the corrective action taken.

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

(a) Follow the radiation safety and handling instructions approved by the department, the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing 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 ((~~shall~~)) must be maintained for inspection by the department and ((~~shall~~)) 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.

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

**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.*

*Note: No person may 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 ((~~or~~)), by-product material or radioactive material, whose subsequent possession, use, transfer and disposal by all other persons ((~~who are~~)) exempted from regulatory requirements may be obtained only from the ((~~United States Nuclear Regulatory Commission~~)) 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 multicurie 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 shall 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 shall 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 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 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 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.

AMENDATORY SECTION (Amending WSR 98-13-037, filed 6/8/98, effective 7/9/98)

**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 ((~~United States Nuclear Regulatory Commission~~)) 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 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 reasonable 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 manufac-

tured, 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 ((~~United States Nuclear Regulatory Commission~~)) 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 ((~~United States Nuclear Regulatory Commission's~~)) NRC's or agreement state's regulation equivalent to WAC 246-233-010(4) and a copy of the ((~~United States Nuclear Regulatory Commission's~~)) 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 ((~~United States Nuclear Regulatory Commission~~)) 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 shall identify each general licensee by name and address, an individual by name ((~~and/~~))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 shall be submitted within thirty 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 shall so indicate;

(f) Provide certain other reports as follows:

(i) Report to the ((~~United States Nuclear Regulatory Commission~~)) NRC all transfers of industrial products or devices to persons for use under the ((~~United States Nuclear Regulatory Commission~~)) 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 shall identify each general licensee by name and address, an individual by name ((~~and/~~))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 shall be submitted within thirty 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 ((~~United States Nuclear Regulatory Commission~~)) NRC licensees during the reporting period,

this information shall be reported to the ((~~United States Nuclear Regulatory Commission~~)) NRC;

(v) If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall 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 ((~~United States Nuclear Regulatory Commission~~)) NRC or of an agreement state. The records shall be maintained for a period of two years and shall 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.

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**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 ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing 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 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 ((~~rems~~)) centigray (15 rem)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter . . . . . 200 ((~~rems~~)) centigray (200 rem)

Other organs . . . . . 50 ((~~rems~~)) 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 ((~~isotope~~)) 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*, are subject to a general license or the equivalent, and the regulations of the ((~~United States Nuclear Regulatory Commission~~)) NRC or a state with which the ((~~United States Nuclear Regulatory Commission~~)) NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

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

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

CAUTION - RADIOACTIVE MATERIAL

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

*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.

(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 ((~~isotope~~)) 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.

(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 sig-

nificant 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 ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing 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 shall 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 shall 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 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 ((~~shall, prior to the transfer to the intended user or the initial transfer to an intermediate person, if used:~~)) 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 much also be provided to the intended user before initial transfer to the intermediate person.

(a) ((~~Furnish to the intended user and to each person to whom a device is transferred as an intermediary, the following~~)) 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) ((~~Furnish to the intended user~~)) If a device containing radioactive material is to be transferred for use in another jurisdiction ((~~and to each person to whom a device is transferred as an intermediary, the following~~)) 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((~~, contained in the United States Nuclear Regulatory Commission's, agreement state's, or licensing state's regulation~~)). If a copy of ((~~the general license in~~)) WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250 is ((~~furnished~~)) provided to ((~~such a person,~~)) a prospective general licensee in lieu of the NRC's or the agreement state's regulations, it shall be accompanied by a note explaining that the use of the device is regulated by the ((~~United States Nuclear Regulatory Commission,~~)) NRC or the agreement state ((~~or licensing state under requirements substantially the same as those in WAC 246-233-020~~)). 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 ((~~U.S. Nuclear Regulatory Commission~~)) 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 ((~~such~~)) 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) ((~~Such~~)) Each report ((~~shall~~)) 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 ((~~shall be submitted along~~)) 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 ((~~quantity and type~~)) 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 ((~~prior to~~)) before its possession by the user, the report ((~~shall~~)) must include ((~~identification of~~)) the same information for both the intended 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 ((~~persons generally licensed~~)) 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 ((~~shall~~)) must so indicate.

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

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

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

(i) ((~~Report to the United States Nuclear Regulatory Commission all transfers of such devices to persons for use under the United States Nuclear Regulatory Commission general license in Section 31.5 of 10 C.F.R. Part 31 and all receipts of devices therefrom.~~)) 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) ((~~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 246-233-020 and all receipts of devices from persons generally licensed under WAC 246-233-020 or equivalent.~~)) 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((~~s shall~~)) 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 shall 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 ((~~and~~)), 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 ((~~prior to~~)) before its possession by the user, the report ((~~shall~~)) must include ((~~identification of each intermediate person by name, address, contact, and relationship to the intended user~~)) 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 ((~~shall be submitted~~)) must cover each calendar quarter, must be filed within thirty days ((~~after~~)) of the end of ((~~each~~)) the calendar quarter ((~~in which such a device is transferred to the generally licensed person~~)), and ((~~shall~~)) must clearly indicate the period covered by the report.

(viii) The report ((~~shall~~)) 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 ((~~United States Nuclear Regulatory Commission~~)) or from NRC licensees during the reporting period, this information shall be reported to the ((~~United States Nuclear Regulatory Commission~~)) NRC.

(x) If no transfers have been made to or from general licensees within ((~~a particular~~)) an agreement state during the reporting period, this information shall be reported to the responsible ((~~department~~)) agreement state agency upon request of the ((~~department~~)) 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 ((~~shall~~)) 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 ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement

state, ((~~or a licensing state,~~)) records of final disposition required under this subsection (4) ((~~of this section~~)) (e).

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

**WAC 246-235-097 Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.** An application for a specific license to manufacture or distribute radioactive material for use under the general license of WAC 246-233-040 will be approved if:

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

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) Iodine-125 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(b) Iodine-131 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(c) Carbon-14 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(d) Hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerels (50 microcuries) each;

(e) Iron-59 in units not exceeding 740 kilobecquerels (20 microcuries) each;

(f) Cobalt-57 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(g) Selenium-75 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(h) Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 185 becquerels (0.005 microcurie) of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerels (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1850 kilobecquerels (50 microcuries) of hydrogen-3 (tritium); 740 kilobecquerels (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 185 becquerels (0.005 microcurie) of americium-241 each; and

(b) Displaying the radiation caution symbol described in WAC 246-221-120 (1)(a) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for internal or external use in humans or animals."

(4) 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:

(a) This radioactive material may 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, ac-

quisition, possession, use and transfer are subject to the regulations and a general license of the ((~~United States Nuclear Regulatory Commission~~)) NRC or of a state with which the ((~~commission~~)) NRC has entered into an agreement for the exercise of regulatory authority.

.....
Name of manufacturer

(b) This radioactive material may 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~~)) the NRC or an agreement state.

.....
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements ((~~set out~~)) in WAC 246-221-170 of these ((~~regulations~~)) rules.

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

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

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

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

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

(ii) Licensed as a nuclear pharmacy by the state board of pharmacy;

(iii) Registered or licensed as a radiopharmaceutical production facility or nuclear pharmacy with the ((~~U.S. Nuclear Regulatory Commission~~)) NRC or a state agency;

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

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

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

safe handling and storage of radiopharmaceuticals by medical use licensees; and

(d) The applicant satisfies the following labeling requirements:

(i) Those specified by the state board of pharmacy in WAC 246-903-020 for both commercial and noncommercial distribution;

(ii) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "caution-radioactive material" or "danger-radioactive material," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than one hundred days, the time may be omitted;

(iii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "caution-radioactive material" or "danger-radioactive material" and an identifier that allows the syringe, vial, or other container to be correlated with the information on the transport radiation shield label; and

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

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

(a) Request authorization to produce accelerator-produced radionuclides at a radionuclide production facility within their consortium to prepare approved radioactive drugs for use only by licensees within that consortium. The applicant must have a current state radioactive materials license or evidence of an existing license issued by ((~~U.S. Nuclear Regulatory Commission or another~~)) an agreement state.

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

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

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

(3) A nuclear pharmacy licensee:

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

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in WAC 246-240-010;

(ii) This individual meets the state board of pharmacy requirements in WAC 246-903-030, Nuclear pharmacists, and the requirements of WAC 246-240-081 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with (d) of this subsection.

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

(d) May designate a pharmacist as an authorized nuclear pharmacist if:

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

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

(e) Shall provide to the department a copy of each individual's letter of notification from the state board of pharmacy 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.

((~~(3)~~)) (4) A manufacturer or nuclear pharmacy licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals, prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests on each instrument before initial use, periodically, and following repair, ((~~on each instrument~~)) for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

((~~(4)~~)) (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 ((~~isotope~~)) 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.

((~~(5)~~)) (6) Nothing in this section relieves the licensee from complying with applicable FDA, ((~~other~~)) federal, and state requirements governing radiopharmaceuticals.

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

**WAC 246-235-102 Manufacture and distribution of sources or devices containing radioactive material for medical use.** An application for a specific license to manufacture and distribute sources and devi-

ces containing radioactive material to persons licensed under chapter 246-240 WAC for use as a calibration, transmission, or reference source or for the uses listed in WAC 246-240-251, 246-240-301, and 246-240-351 will be approved if:

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

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form and amount;

(b) Details of design and construction of the source or device;

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(d) For devices containing radioactive material, the radiation profile of a prototype device;

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(f) Procedures and standards for calibrating sources and devices;

(g) Legend and methods for labeling sources and devices as to their radioactive content; and

(h) Instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided that instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the named source or device is licensed by the department for distribution to persons licensed under chapter 246-240 WAC or under equivalent regulations of the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~)): Provided that the labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.

(4) If the applicant desires that the source or device be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(5) In determining the acceptable interval for test of leakage of radioactive material, the department will consider information that 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 sources or devices or similarly designed and constructed sources or devices.

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

**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 shall be measured by direct counting of the source.

(2) *Dry wipe test*. The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall 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 shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall 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 shall be immersed in water at room temperature for a period of twenty-four consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall 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 shall be repeated.

(6) *Observations*. Removal of more than 0.005 microcurie (185 becquerels) of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the department or the ((~~U.S. Nuclear Regulatory Commission~~)) NRC shall 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.

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

**WAC 246-235-105 Manufacture, assembly or distribution of radioactive material exempt from regulation.** (((~~(1) *Licensing the introduction of radioactive material into products in exempt concentrations.* In addition to the requirements set forth in WAC 246-235-020, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under WAC 246-232-010(1) will be issued if:~~

~~(a) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and~~

~~(b) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in WAC 246-232-130, Schedule C, that reconstruction of the radioactive material in concentrations exceeding those in WAC 246-232-130, Schedule C, is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to a human being.~~

~~(c) Each person licensed under subsection (1) of this section shall file an annual report with the department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product and material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to subsection (1) of this section during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within thirty days thereafter.~~

~~(2) *Licensing the distribution of certain radioactive material in exempt quantities.**~~

~~*Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing source material or radioactive material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the department or the United States Nuclear Regulatory Commission, Washington, D.C. 20555.~~

~~(a) An application for a specific license to distribute naturally occurring and accelerator-produced radioactive material (NARM) to persons exempted from these regulations pursuant to WAC 246-232-010 (2)(b) will be approved if:~~

~~(i) The radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;~~

~~(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and~~

~~(iii) The applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.~~

~~(b) The license issued under (a) of this subsection is subject to the following conditions:~~

~~(i) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.~~

~~(ii) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to WAC 246-232-010 (2)(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.~~

~~(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:~~

~~(A) Identifies the radionuclide and the quantity of radioactivity; and~~

~~(B) Bears the words "radioactive material."~~

~~(iv) In addition to the labeling information required by (b)(iii) of this subsection, the label affixed to the immediate container, or an accompanying brochure, shall:~~

~~(A) State that the contents are exempt from licensing state requirements;~~

~~(B) Bear the words "Radioactive material Not for human use Introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited Exempt quantities should not be combined"; and~~

~~(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.~~

~~(c) Each person licensed under (a) of this subsection shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under WAC 246-232-010 (2)(b) or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30, and shall be filed within thirty days thereafter. If no transfers of radioactive material have been made pursuant to subsection (2) of this section during the reporting period, the report shall so indicate.~~

~~(3) *Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors.* An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons ex-~~

~~empt under WAC 246-232-012 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 C.F.R. Part 32.~~

~~*Note: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing source material or radioactive material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the department or the United States Nuclear Regulatory Commission, Washington, D.C. 20555.))~~

A person may not 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.

AMENDATORY SECTION (Amending WSR 94-01-073, filed 12/9/93, effective 1/9/94)

**WAC 246-235-130 Appendix—General laboratory rules for safe use of unsealed sources.** (1) In addition to the requirements ((~~set forth~~)) in WAC 246-235-020, a specific licensee who uses unsealed, unplated ((~~and/~~))or liquid sources shall possess adequate facilities including ventilation systems which are compatible with the proposed uses: and,

(2) Possess, use, and store((~~,~~)) radioactive material((~~s~~)) in accordance with, but not limited to, the following:

(a) Receive, handle, and store radioactive material((~~s~~)) only at specifically designated locations within the applicant's facility. Vessels containing radioactive material must be labeled as required by chapter 246-221 WAC.

(b) Wear disposable gloves at all times when handling dispersible radioactive material or potentially contaminated items.

(c) Wear personnel monitoring devices (film badge ((~~and/~~)), OSL, or TLD), when required, at all times when working with, or in the vicinity of, radioactive materials. Extremity doses shall be considered ((~~in~~)) when evaluating the need for separate extremity dosimeters. Extremity dosimetry should be worn when working with millicurie or greater quantities of material (excluding low energy beta emitters and pure alpha emitters). Monitoring devices, when not in use, ((~~shall~~)) must be stored only in a designated low-background area. Calculations based on ((~~whole body badge~~)) whole-body dosimeter results for photon-emitters may be used in lieu of separate extremity dosimeters.

(d) Use remote tools, lead shields, lead-glass shields, ((~~and/~~))or plexiglass shields as appropriate.

(e) Prohibit eating, chewing, drinking, smoking, and application of cosmetics in any area where radioactive material is used or stored.

(f) Do not store food, drink or personal effects in any area, container, or refrigerator designated for radioactive materials use or storage.

(g) Do not pipette radioactive materials or perform any similar operation by employing mouth suction.

(h) Use disposable absorbent material with impervious backing to cover work surfaces where spillage is possible.

(i) Properly dress and protect open wounds on exposed body surfaces before working with radioactive materials.

(j) Wear laboratory coats when working with radioactive material. Potentially contaminated laboratory coats shall not be worn outside the immediate work area.

(k) Nuclides in gaseous or volatile form, or with a high potential for volatilization shall be used only in areas with adequate ventilation systems.

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**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.

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**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~~)) a general ((~~license does~~)) licensee under this section is not ((~~authorize the~~)) authorized to manufacture, ((~~production~~)) produce, transfer, ((~~receipt~~)) receive, ((~~possession or~~)) possess, use ((~~of~~)), import or export radioactive material, except as authorized by a specific license.

AMENDATORY SECTION (Amending WSR 98-13-037, filed 6/8/98, effective 7/9/98)

**WAC 246-233-010 General licenses—Source material.** (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 li-

cense 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~~)) subsection, 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~~)) subsection 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~~)) NRC 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~~)) NRC 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~~)) subsection 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~~)) subsection 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~~)) subsection.

(ii) The registrant possessing or using depleted uranium under the general license established by ((~~paragraph (4)~~))(a) of this ((~~section~~)) subsection shall report in writing to the department any 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~~)) subsection:

(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~~)) subsection 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~~)) NRC's or agreement state's regulation equivalent to ((~~paragraph (4)~~))(a) of this ((~~section~~)) subsection 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~~)) NRC 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~~)) NRC pursuant to 10 C.F.R. 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~~)) subsection 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.

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

**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 material((~~s~~)) 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 material((~~s~~)) under a specific license issued under chapter 246-235 WAC.

(3) Any person who acquires, receives, possesses, uses, or transfers ((~~by-product~~)) radioactive 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.

(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.

AMENDATORY SECTION (Amending WSR 09-06-003, 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~~)) NRC for use pursuant to Section 31.3 of 10 C.F.R. 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~~)) 1.85 gigabecquerels (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.

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

**WAC 246-233-020 ((~~General license—~~))Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.** (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 federal, 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 an equivalent specific license issued by the ((~~Nuclear Regulatory Commission,~~)) NRC or 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,~~)) NRC or an agreement state ((~~or licensing state~~))**. The devices ((~~shall~~)) must 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 C.F.R. 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 material((~~s~~)), 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~~)) issued by the department ((~~or from~~)), the ((~~United States Nuclear Regulatory Commission~~)) NRC or ((~~from any~~)) an 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~~)) must show the results of tests. The records also ((~~shall~~)) must show the dates of performance and the names of persons performing, testing, installing, servicing, and removing from installation ((~~concerning the~~)) radioactive material((~~,~~)) and its shielding or containment. Records of tests for leakage of radioactive material required by (b) of this subsection ((~~shall~~)) must be ((~~maintained~~)) retained 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~~)) must be ((~~maintained~~)) retained 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~~)) must be ((~~maintained~~)) retained 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~~)) Shall immediately suspend operation of the device if there is 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 microcurie((~~s~~))) or more removable radioactive material((~~, shall immediately suspend operation of the device~~)). The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license ((~~from~~)) issued by the department, the ((~~United States Nuclear Regulatory Commission,~~)) NRC 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,~~)) or as otherwise approved by the department. Within thirty days, ((~~furnish to~~)) the licensee must send 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 microcurie((~~s~~))) 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)(i) Shall not abandon the device containing radioactive material;

(ii) Shall not export the device containing radioactive material except in accordance with the provisions of 10 C.F.R. 110;

(g) Except as provided in (h) of this subsection, ((~~shall~~)) must transfer or dispose of the device containing radioactive material only by transfer to a person ((~~holding~~)) with a specific license ((~~of~~)) issued by the department, the ((~~United States Nuclear Regulatory Commission~~)) NRC, or an agreement state, ((~~or a licensing state whose specific license~~)) which authorizes the person to receive the device ((~~and~~)). Within thirty days after export or transfer of a device to a specific licensee ((~~shall furnish~~)), the general licensee must send a report to the department ((~~a report~~)), containing ((~~identification~~)) the identity of the device ((~~by manufacturer's~~)) and manufacturer (or initial ((~~transferor's) name~~)) transferor), model number, ((~~and~~)) serial number, the nuclide(s), and activity of radioactive material contained in the devices; 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; however, a specific licensee may transfer a device for possession and use under its own specific license without prior approval, if the specific licensee:

(i) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(ii) Removes, alters, covers, or clearly and unambiguously augments the existing label, so that the device is labeled in compliance with WAC 246-221-120(9); however, the manufacturer, model number, and serial number must be retained;

(iii) Obtains the manufacturer's or initial transferor's maintenance information applicable under the specific license (such as leak test procedures); and

(iv) Reports the transfer under WAC 246-233-020 (3)(g).

(h) Shall transfer the device to another general licensee only if:

(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~~)) by the label of the device ((~~and~~)). Within thirty days of the transfer, the transferor shall report to the department: The ((~~manufacturer's~~)) name of the manufacturer (or ((~~transferor's) name~~)) initial transferor), model number, ((~~and~~)) serial number ((~~of device~~)), and the source, nuclide(s), and original activity contained in the device(s) 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 action((~~s~~)) to ensure compliance with the appropriate regulations and requirements; or

(ii) ((~~Where~~)) The device is held in storage by an intermediate person 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, or theft or loss of

((~~licensed~~)) radioactive 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, 3.7 megabecquerels (100 microcuries) of Radium-226, 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~~)) When registering devices, the general licensee shall ((~~furnish~~)) provide 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~~)) verification 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~~)) WAC 246-232-040, Reciprocal recognition of licenses describes how persons licensed by the ((~~U.S. Nuclear Regulatory Commission,~~)) NRC 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;~~)) may obtain approval to work in Washington.

(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 subsection (3)(b) of this ((~~subsection~~)) section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and 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;

(n) Must 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 the same time period, request a longer period to supply the information by providing a written justification for the extension request.

(4) The general license in subsection (1) of this section does not authorize the manufacture, import, or export of devices containing radioactive material. A person must not export the device containing radioactive material except in accordance with NRC's regulations, including 10 C.F.R. Part 110, and in accordance with other applicable federal, state, and local regulations including, but not limited to, the U.S. Department of Commerce, U.S. Department of Revenue, U.S. Department of Transportation, and any other applicable jurisdiction for each export.

(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.

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

**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 Hydrogen-3 (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 Hydrogen-3 (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~~)) NRC, 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 C.F.R. Part 32 of the regulations of the ((~~United States Nuclear Regulatory Commission~~)) NRC.

(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 Hydrogen-3 (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.

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

**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~~)) NRC 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 C.F.R. Part 32 of the regulations of the ((~~United States Nuclear Regulatory Commission~~)) NRC.

(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~~)) issued by the ((~~United States Nuclear Regulatory Commission~~)) NRC 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.

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

**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~~)) NRC which authorizes that person to receive, possess, use and transfer special nuclear material.

(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 or the NRC 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 or the NRC 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~~)) NRC pursuant to Section 32.57 of 10 C.F.R. Part 32 or Section 70.39 of 10 C.F.R. 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 C.F.R. Part 32 or Section 70.39 of 10 C.F.R. Part 70 of the regulations of the ((~~United States Nuclear Regulatory Commission~~)) NRC.

(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~~)) NRC 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~~)) an agreement state or NRC. 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~~)) issued by the department, the ((~~United States Nuclear Regulatory Commission~~)) NRC, 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.

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

**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 lab-

oratory 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 material((~~s~~)) 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 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 annual 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 mate-

rial 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~~)) NRC, or an 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~~)) NRC, or ((~~any~~)) an 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~~)) rules and a general license of an agreement state or 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~~)) NRC.

.....
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~~)) rules and a general license of ((~~a licensing~~)) an agreement state or the NRC.

.....
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 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~~)) rules.

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

**WAC 246-232-001 Purpose and scope.** (1) This chapter prescribes rules governing licensing of radioactive material. ((~~A~~)) No person ((~~may not~~)) shall manufacture, produce, transfer, receive, acquire, own, possess, or use((~~, transfer, own or acquire~~)) radioactive material except:

(a) As authorized in a specific or general license issued under chapters 246-233 or 246-235 WAC;

(b) As authorized in a specific or general license issued under regulations of NRC or an agreement state equivalent to chapters 246-233 or 246-235 WAC; or

(c) As otherwise provided in this chapter.

(2) In addition to the requirements of this chapter, and chapters 246-233 or 246-235 WAC, all licensees must comply with chapters 246-220, 246-221, 246-222, 246-231, 246-247, and 246-254 WAC. Licensees engaged in the practice of nuclear medicine are subject to chapter 246-240 WAC, licensees engaged in industrial radiographic operations are subject to chapter 246-243 WAC, licensees using sealed sources in the healing arts are subject to chapter 246-240 WAC, licensees using radioactive material in well logging and subsurface tracer studies are subject to chapter 246-244 WAC, licensees engaged in land disposal of radioactive waste are subject to chapter 246-250 WAC, and licensees owning or operating uranium or thorium mills and associated mill tailings are subject to chapter 246-252 WAC.

(3) 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.

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

**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, ((~~owns, or~~)) 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 246-233 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 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 if the glaze contains twenty percent or less by weight source material; and

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

(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 contained in finished optical lenses if each lens contains thirty percent or less by weight of thorium. The exemption contained in this subparagraph shall not be deemed to authorize either:

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

(ii) The receipt, possession, use or transfer of thorium 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.

AMENDATORY SECTION (Amending WSR 01-02-068, filed 12/29/00, effective 1/29/01)

**WAC 246-232-007 Exemption of certain depleted uranium items.** (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 or transfers:

(a) Depleted uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights if:

(i) The counterweights are manufactured in accordance with a specific license issued by the ((~~United States Nuclear Regulatory Commission~~)) NRC authorizing distribution by the licensee pursuant to 10 C.F.R. Part 40;

(ii) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM"*;

(iii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"*; and

(iv) The exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweight other than repair or restoration of any plating or other covering;

*Note: The requirements specified in (c) (v) (B) and (C) of this subsection need not be met by counterweights manufactured prior to December 31, 1969: Provided, That such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," as previously required by the ((~~regulations~~)) rules.

(b) Natural or depleted uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and the uranium metal is encased in mild steel or in an equally fire resistant metal of a minimum wall thickness of 3.2 millimeters.

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

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

**WAC 246-232-008 Exemption of certain timepieces, hands or dials.** A person is exempt from ((~~these regulations~~)) 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: ((~~Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission~~)) 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 megabecquerels (25 millicuries) ((~~or less~~)) of tritium per timepiece;

(b) 185 megabecquerels (5 millicuries) ((~~or less~~)) of tritium per hand;

(c) 555 megabecquerels (15 millicuries) ((~~or less~~)) of tritium per dial (bezels when used shall be considered as part of the dial);

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

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

(f) 2.22 megabecquerels (60 microcuries) ((~~or less~~)) of promethium-147 per watch dial or 4.44 megabecquerels (120 microcuries) ((~~or less~~)) 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, 1 microgray (0.1 millirad) per hour at 10 centimeters from any surface;

(b) For pocket watches, 1 microgray (0.1 millirad) per hour at 1 centimeter from any surface;

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

(3) 37 kilobecquerels (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to ((~~the effective date of these regulations~~)) November 30, 2007.

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

**WAC 246-232-009 Exemption of certain items containing radioactive material.** A person is exempt from ((~~these regulations~~)) 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: ((~~Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission~~)) 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) ((~~Lock illuminators containing 555 megabecquerels (15 millicuries) or less of tritium or 74 megabecquerels (2 millicuries) or less of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 10 micrograys (1 millirad) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

~~(2) Precision~~)) Balances of precision containing not more than 37 megabecquerels (1 millicurie) ((~~or less~~)) of tritium per balance or 18.5 megabecquerels (0.5 millicurie) ((~~or less~~)) of tritium per balance part manufactured before December 17, 2007.

((~~(3) Automobile shift quadrants containing 925 megabecquerels (25 millicuries) or less of tritium.~~

~~(4)~~)) (2) Marine compasses containing not more than 27.8 gigabecquerels (750 millicuries) ((~~or less~~)) of tritium gas and other marine navigational instruments containing not more than 9.25 gigabecquerels

(250 millicuries) ((~~or less~~)) of tritium gas manufactured before December 17, 2007.

((~~(5) Thermostat dials and pointers containing 925 megabecquerels (25 millicuries) or less of tritium per thermostat.~~

~~(6)~~)) (3) Ionization chamber smoke detectors containing not more than 37 kilobecquerels (1 microcurie) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(4) Electron tubes* ((~~if~~)) 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 (1 millirad) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber:

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

(b) 37 kilobecquerels (1 microcurie) ((~~or less~~)) of cobalt-60;

(c) 185 kilobecquerels (5 microcuries) ((~~or less~~)) of nickel-63;

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

(e) 185 kilobecquerels (5 microcuries) ((~~or less~~)) of cesium-137;

(f) 1.11 megabecquerels (30 microcuries) ((~~or less~~)) of promethium-147((~~;~~

~~(g) 37 kilobecquerels (1 microcurie) or less of radium-226:~~)).

*Note: For purposes of this ((~~subdivision~~)) 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)~~)) (5) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more ((~~but not to exceed 10 exempt~~)) sources of radioactive material((~~.~~)), provided that:

(a) Each ((~~individual~~)) source ((~~shall not exceed 1.85 kilobecquerels (0.05 microcuries) of americium-241 or the applicable~~)) contains not more than one exempt quantity set forth in WAC 246-232-120, Schedule B((~~.~~)), exempt quantities of radioactive materials; and

(b) ((~~An individual source may contain more than one radionuclide but the total quantity in the individual source shall not exceed unity based on the sum of the fractional parts of one or more of the exempt quantities set forth in WAC 246-232-120, Schedule B. For purposes of this subsection, 1.85 kilobecquerels (0.05 microcuries) of americium-241 is considered an exempt quantity.~~

~~(8) Spark gap irradiators containing 37 kilobecquerels (1 microcurie) or less of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.~~)) 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.

AMENDATORY SECTION (Amending WSR 01-02-068, filed 12/29/00, effective 1/29/01)

**WAC 246-232-010 Exempt concentrations and exempt quantities.** This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(1) Exempt concentrations.

(a) Except as provided in (b) of this subsection, 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, products or materials containing radioactive material in concentrations ((~~less than or equal to~~)) in excess of those ((~~listed~~)) in WAC 246-232-130, Schedule C, exempt concentrations.

(b) 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 ((~~(a) of~~)) this ((~~subsection~~)) section or equivalent regulations of the ((~~United States Nuclear Regulatory Commission, any~~)) NRC or an agreement state ((~~or licensing state~~)), except in accordance with a specific license issued ((~~under WAC 246-235-105 or the general license provided in WAC 246-232-040~~)) by the NRC, Washington, D.C. 20555.

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in WAC 246-232-130, Schedule C, and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such manufacture or introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Exempt quantities.

(a)(i) Except as provided in (b) ((~~and (c)~~)) through (d) of this subsection, ((~~a~~)) any person is exempt from ((~~these regulations~~)) the requirements for a license and from this chapter and chapters 246-233 and 246-235 WAC to the extent that such person receives, possesses, uses, transfers, owns, or acquires, and does not apply radioactive material to, or incorporate radioactive material into, radioactive material in individual quantities, each of which ((~~is less than or equal to~~)) does not exceed the applicable quantity set forth in WAC 246-232-120, Schedule B, exempt quantities of radioactive materials.

(ii) Any person who possesses radioactive material received or acquired under the general license is exempt from the requirements for a license set forth in chapters 246-333, 246-235 WAC, and this chapter to the extent that such person uses, transfers, or owns such radioactive material. Such exemption does not apply for Radium-226 or use by agreement states whose regulations formerly contained a general license for small quantities of radioactive material.

(b) This subsection does not authorize the production, packaging ((~~or~~)), repackaging, or transfer of radioactive material for the purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(c) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in WAC 246-232-120, Schedule B, exempt quantities of radioactive materials, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under ((~~subsection (2) of~~)) this section or equivalent ((~~regulations~~)) rules of the ((~~United States Nuclear Regulatory Commission~~)) NRC or ((~~any~~)) an agreement state ((~~or licensing state~~)), except in accordance with a specific license issued by the ((~~United States Nuclear Regulatory Commission, under Section 32.18 of 10 C.F.R. Part 32 or by the department under WAC 246-235-105 which license states that the radioactive material may be transferred by the licensee to persons exempt under subsection (2) of this section or the equivalent regulations of the United States Nuclear Regulatory Commission or any agreement state or licensing state~~)) NRC, Washington, D.C. 20555.

(d) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in WAC 246-232-120, Schedule B, exempt quantities of radioactive materials, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by these rules.

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

**WAC 246-232-011 Exemption of certain self-luminous products containing radioactive material(s).** (1) Hydrogen-3 (Tritium), krypton-85, or promethium-147. A person is exempt from ((~~these regulations~~)) 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 manufacture, process, produce, apply radioactive material to, incorporate radioactive material into, or initially transfer for sale or distribution, self-luminous products containing hydrogen-3 (tritium), krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, imported or initially transferred in accordance with a specific license issued by the ((~~United States Nuclear Regulatory Commission under Section 32.22 of 10 C.F.R. Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements~~)) NRC. The exemption in this subsection does not apply to hydrogen-3, (tritium), krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(2) ((~~Radium-226. A person is exempt from these regulations to the extent that the person receives, possesses, uses, transfers or owns articles containing less than 3.7 kilobecquerels (0.1 microcurie) of radium-226 which were manufactured prior to October 1983.~~)) 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.

AMENDATORY SECTION (Amending WSR 01-02-068, filed 12/29/00, effective 1/29/01)

**WAC 246-232-012 Exemption of certain gas and aerosol detectors containing radioactive material.** (1) A person is exempt from ((~~these regulations~~)) 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, manufacture, process or produce, radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards if the detectors have been manufactured, imported, or transferred in accordance with a specific license issued by the ((~~United States Nuclear Regulatory Commission* or an agreement state, under Section 32.26 of 10 C.F.R. Part 32, or licensing state under WAC 246-235-105, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements~~)) NRC.

((~~*Note: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the United States Nuclear Regulatory Commission, Washington, D.C. 20555.~~))

(2) ((~~Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under subsection (1) of this section if the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device and if the device meets the requirements of WAC 246-235-105.~~

~~(3) Gas and aerosol detectors containing naturally occurring and accelerator-produced radioactive material (NARM) previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under subsection (1) of this section if the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and if the device meets the requirements of WAC 246-235-105.~~)) 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.

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

**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 ((~~set forth in~~)) 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 kilobequerels (1 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 ((~~shall~~)) 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 ((~~shall apply for and receive~~)) must do so in accordance with a specific license ((~~from~~)) issued by the ((~~United States Nuclear Regulatory Commission under Section 32.21 of 10 C.F.R. Part 32~~)) NRC, Washington, D.C. 20555.

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

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**WAC 246-232-020 Types of licenses.** Licenses for radioactive material((~~s~~)) are of two types: General and specific.

(1) A general license((~~s~~)) is provided ((~~in chapter 246-233 WAC are~~)) by regulation and grants authority to a person for certain activities involving radioactive material, and is effective without ((~~the~~)) filing ((~~of~~)) an application((~~s~~)) with the department or ((~~the~~)) issuance of licensing documents to ((~~the~~)) a particular person((~~s, although~~)). However, registration or the filing of a certificate with the department may also be required by the particular general license. The general licensee is subject to all other applicable ((~~portions of these regulations~~)) rules and any limitations of the general license.

(2) ((~~Specific licenses require the submission~~)) The department issues a specific license to a named person, after review and approval of an application ((~~to the department and the issuance of a licensing document by the department~~)). The licensee is subject to all applicable ((~~portions of these regulations as well as~~)) rules, including chapter 246-235 WAC, Radioactive materials - Specific licenses, and any limitations specified in the ((~~licensing document~~)) specific license. ((~~(See chapter 246-235 WAC.)~~))

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**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) ((~~Subject to these regulations, any~~)) A person ((~~who holds~~)) authorized by a ((~~specific~~)) license ((~~from~~)) issued by the ((~~United States Nuclear Regulatory Commission~~)) NRC or ((~~any~~)) an agreement state ((~~or licensing state, and~~)), may obtain authorization from the department to work in Washington state provided:

(a) The out-of-state license is issued by the ((~~agency having~~)) NRC or agreement state with jurisdiction where the licensee maintains an office for directing the licensed ((~~activity~~)) work and ((~~at which~~)) for retaining radiation safety records ((~~are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this~~));

(b) The out-of-state licensee must not possess or use radioactive materials or conduct authorized work in Washington state for ((~~a period not in excess of~~)) more than one hundred eighty days in that twelve month period which ((~~commences~~)) starts the date approval is granted, and the appropriate fee is received((~~,~~)) by the department ((~~provided that:~~

~~(a)~~)), as required in chapter 246-254 WAC;

(c) The out-of-state licensing document ((~~does not limit the activity authorized by such document to specified installations or locations~~)) authorizes the work conducted;

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

((~~(c)~~)) (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 ((~~and pays or has paid the appropriate fee (refer to chapter 246-254 WAC),~~)) at least three days ((~~prior to~~)) before each entry ((~~to the~~)) into Washington state to ((~~engage in such activity~~)) conduct licensed work.

(i) The written notification must be sent to the Radioactive Materials Section, Department of Health, ((~~Mailstop~~)) P.O. Box 47827, Olympia, Washington 98504-7827 ((~~and the fee should be sent to Washington State Department of Health, Revenue Accounting, P.O. Box 1099, Olympia, Washington 98504. Such~~)). Fax, e-mail, or other notifications may be approved by the department.

(ii) The written notification ((~~shall indicate the~~)) must include use and storage location(s), ((~~period,~~)) start and end dates of licensed work, and type of proposed possession and use ((~~within the~~)) in Washington state, and ((~~shall be accompanied by copies of the pertinent~~)) must include licensing documents authorizing the licensed work.

(iii) If((~~, for a specific case,~~)) an unexpected need or emergency means the three-day ((~~period~~)) notice is impossible or would impose an undue hardship on the out-of-state licensee, the out-of-state licensee may((~~, upon~~)) telephone ((~~application to~~)) the department (((~~360-236-3220~~)) 360-236-3221), ((~~obtain~~)) for permission to proceed ((~~sooner~~)) immediately.

(iv) The department may waive the requirement for filing additional written notifications during the remainder of the twelve months following the receipt of the initial notification ((~~from a person engaging in activities under the general license provided in this subsection;~~

~~(d)~~)).

(g) The out-of-state licensee ((~~complies with all applicable regulations of the department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the department;~~

~~(e) The out-of-state licensee supplies such other information as the department may request; and~~

~~(f)~~)) 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 ((~~shall~~)) may not transfer or dispose of radioactive material ((~~possessed or used under the general license provided in this subsection~~)) except by transfer to a person((~~:~~

~~(i)~~)) specifically licensed by the department or by the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~)) to receive such material((~~; or~~

~~(ii) Exempt from the requirements for a license for such material under WAC 246-232-010(1)~~)).

(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 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) ((~~Notwithstanding the provisions of subsection (1) of this section, any~~)) A person who holds a specific license issued by the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~)) authorizing the holder to manufacture, ((~~transfer,~~)) 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((~~, transfer, demonstrate or~~)) and service ((~~a~~)) such device in this state in areas not under exclusive federal jurisdiction provided ((~~that~~)):

(a) Such person ((~~shall~~)) must file a report with the department within thirty days after the end of each calendar quarter in which any device is transferred to or from, or installed in this state. Each ((~~such~~)) report ((~~shall~~)) must identify each general licensee to or from whom such device is transferred by name and address, the ((~~type of~~)) device ((~~transferred~~)) 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 ((~~such~~)) a person by the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~));

(c) Such person ((~~shall assure~~)) must ensure that any labels required to be affixed to the device under ((~~regulations~~)) rules of the

authority which licensed the manufacture of the device bear a statement that ((")) removal of ((~~this~~)) the label is prohibited((")); and

(d) The ((~~holder of the~~)) specific ((~~license shall furnish to~~)) 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 ((~~contained~~)) in WAC 246-233-020((~~(4)~~)).

(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 ((~~in order~~)) to prevent undue hazard to public health and safety, or to the environment, or to property.

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**WAC 246-232-050 Terms and conditions of licenses.** (1) Each license issued pursuant to this part shall be subject to all the provisions of the act, as now or hereafter in effect, and to all rules, regulations, and orders of the department.

(2) No license issued or granted under chapters 246-232, 246-233 ((~~and~~)), or 246-235 WAC and no right to possess or ((~~utilize~~)) use radioactive material granted by any license issued pursuant to chapters 246-233 and 246-235 WAC shall be transferred, assigned, or in any manner disposed, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of the act, and ((~~shall~~)) gives its consent in writing.

(3) Each person licensed by the department pursuant to chapters 246-233 and 246-235 WAC shall confine use and possession of the material licensed to the locations and purposes authorized by the license.

(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) Each specific licensee ((~~shall~~)) must notify the department of health, office of radiation protection, in writing, ((~~within five working days~~)) 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) ((~~A person~~)) 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) 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 ((~~and/~~))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) Each specific licensee ((~~shall~~)) must notify the department within five working days if any items in subsection (6) of this section change during bankruptcy proceedings.

(8) The department will consider clean-up costs as part of the licensee's administrative costs if decontamination is necessary to comply with these regulations;

(9) Each general licensee ((~~that is~~)) required to register by WAC 246-233-020 (3)(k) ((~~shall~~)) 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) ((~~A person~~)) 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) 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.

AMENDATORY SECTION (Amending WSR 04-04-055, filed 1/30/04, effective 3/1/04)

**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 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 contamination 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 ((~~facility and/or equipment date specified in 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 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 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 months; or

(d) No principal activities have been conducted for a period of twenty-four 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 decommissioning 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 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 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 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 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 period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted twenty-four-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 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 ((~~and/~~))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 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 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.

AMENDATORY SECTION (Amending Order 184, filed 7/24/91, effective 8/24/91)

**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, ((~~any~~)) 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 ((~~any~~)) a person exempt from the ((~~regulations~~)) rules in this part to the extent permitted under such exemption;

(d) To ((~~any~~)) 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 ((~~United States Nuclear Regulatory Commission, any~~)) NRC or an agreement state ((~~or any licensing state~~)), or to ((~~any~~)) a person otherwise authorized to receive such material by the federal government or ((~~any~~)) an agency thereof, the department, ((~~any~~)) or an agreement state ((~~or any licensing state~~)); or

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

(3) Before transferring radioactive material to a specific licensee of the department, the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~)), or to a general licensee who is required to register with the department, the ((~~United States Nuclear Regulatory Commission,~~)) NRC or an agreement state ((~~or a licensing state~~)) prior to receipt of the radioactive material, the licensee transferring the material ((~~shall~~)) 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 days;

(d) The transferor may obtain other sources of information compiled by a reporting service from official records of the department, the ((~~United States Nuclear Regulatory Commission,~~)) NRC or the licensing agency of an agreement state ((~~or a licensing 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 ((~~United States Nuclear Regulatory Commission,~~)) NRC or the licensing agency of an agreement state ((~~or a licensing state~~)) that the transferee is licensed to receive the radioactive material.

(5) Preparation for shipment and transport of radioactive material ((~~shall~~)) 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, teletherapy sources, portable moisture/density gauge sources, fixed gauge sources, and Mo-99/Tc-99m or Rb-82/Sr-82 generators).

AMENDATORY SECTION (Amending WSR 01-02-068, filed 12/29/00, effective 1/29/01)

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

| Element (atomic number) | ((~~Isotope~~)) 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 | | $1x10^{-3}$ |

| Element (atomic number) | ((~~Isotope~~)) Radionuclide | Column I Gas concentration µCi/ml[1] | Column II Liquid and solid concentration µCi/ml[2] |
|---|---|---|---|
| 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 | $4x10^{-7}$ | $3x10^{-3}$ |
| Cadmium (48) | Cd-109 | | $2x10^{-3}$ |
| | Cd-115m | | $3x10^{-4}$ |
| | Cd-115 | | $3x10^{-4}$ |
| Calcium (20) | Ca-45 | | $9x10^{-5}$ |
| | Ca-47 | | $5x10^{-4}$ |
| Carbon (6) | C-14 | $1x10^{-6}$ | $8x10^{-3}$ |
| Cerium (58) | Ce-141 | | $9x10^{-4}$ |
| | Ce-143 | | $4x10^{-4}$ |
| | Ce-144 | | $1x10^{-4}$ |
| Cesium (55) | Cs-131 | | $2x10^{-2}$ |
| | Cs-134m | | $6x10^{-2}$ |
| | Cs-134 | | $9x10^{-5}$ |
| Chlorine (17) | Cl-38 | $9x10^{-7}$ | $4x10^{-3}$ |
| Chromium (24) | Cr-51 | | $2x10^{-2}$ |
| Cobalt (27) | Co-57 | | $5x10^{-3}$ |
| | Co-58 | | $1x10^{-3}$ |
| | Co-60 | | $5x10^{-4}$ |
| Copper (29) | Cu-64 | | $3x10^{-3}$ |
| Dysprosium (66) | Dy-165 | | $4x10^{-3}$ |
| | Dy-166 | | $4x10^{-4}$ |
| Erbium (68) | Er-169 | | $9x10^{-4}$ |
| | Er-171 | | $1x10^{-3}$ |
| Europium (63) | Eu-152 | | $6x10^{-4}$ |
| | (9.2 h) | | |
| | Eu-155 | | $2x10^{-3}$ |
| Fluorine (9) | F-18 | $2x10^{-6}$ | $8x10^{-3}$ |
| Gadolinium (64) | Gd-153 | | $2x10^{-3}$ |
| | Gd-159 | | $8x10^{-4}$ |
| Gallium (31) | Ga-72 | | $4x10^{-4}$ |
| Germanium (32) | Ge-71 | | $2x10^{-2}$ |
| Gold (79) | Au-196 | | $2x10^{-3}$ |
| | Au-198 | | $5x10^{-4}$ |
| | Au-199 | | $2x10^{-3}$ |
| Hafnium (72) | Hf-181 | | $7x10^{-4}$ |
| Hydrogen (1) | H-3 | $5x10^{-6}$ | $3x10^{-2}$ |

| Element (atomic number) | ((~~Isotope~~)) Radionuclide | Column I Gas concentration µCi/ml[1] | Column II Liquid and solid concentration µCi/ml[2] |
|---|---|---|---|
| Indium (49) | In-113m | | $1x10^{-2}$ |
| | In-114m | | $2x10^{-4}$ |
| Iodine (53) | I-125 | $3x10^{-9}$ | $2x10^{-5}$ |
| | I-126 | $3x10^{-9}$ | $2x10^{-5}$ |
| | I-131 | $3x10^{-9}$ | $2x10^{-5}$ |
| | I-132 | $8x10^{-8}$ | $6x10^{-4}$ |
| | I-133 | $1x10^{-8}$ | $7x10^{-5}$ |
| | I-134 | $2x10^{-7}$ | $1x10^{-3}$ |
| Iridium (77) | Ir-190 | | $2x10^{-3}$ |
| | Ir-192 | | $4x10^{-4}$ |
| | Ir-194 | | $3x10^{-4}$ |
| Iron (26) | Fe-55 | | $8x10^{-3}$ |
| | Fe-59 | | $6x10^{-4}$ |
| Krypton (36) | Kr-85m | $1x10^{-6}$ | |
| | Kr-85 | | $3x10^{-6}$ |
| Lanthanum (57) | La-140 | | $2x10^{-4}$ |
| Lead (82) | Pb-203 | | $4x10^{-3}$ |
| Lutetium (71) | Lu-177 | | $1x10^{-3}$ |
| Manganese (25) | Mn-52 | | $3x10^{-4}$ |
| | Mn-54 | | $1x10^{-3}$ |
| | Mn-56 | | $1x10^{-3}$ |
| Mercury (80) | Hg-197m | | $2x10^{-3}$ |
| | Hg-197 | | $3x10^{-3}$ |
| | Hg-203 | | $2x10^{-4}$ |
| Molybdenum (42) | Mo-99 | | $2x10^{-3}$ |
| Neodymium (60) | And-147 | | $6x10^{-4}$ |
| | And-149 | | $3x10^{-3}$ |
| Nickel (28) | Ni-65 | | $1x10^{-3}$ |
| Niobium (Columbium)(41) | Nb-95 | | $1x10^{-3}$ |
| | Nb-97 | | $9x10^{-3}$ |
| Osmium (76) | So-185 | | $7x10^{-4}$ |
| | So-191m | | $3x10^{-2}$ |
| | So-191 | | $2x10^{-3}$ |
| | So-193 | | $6x10^{-4}$ |
| Palladium (46) | Pd-103 | | $3x10^{-3}$ |
| | Pd-109 | | $9x10^{-4}$ |
| Phosphorus (15) | P-32 | | $2x10^{-4}$ |
| Platinum (78) | Pt-191 | | $1x10^{-3}$ |
| | Pt-193m | | $1x10^{-2}$ |
| | Pt-197m | | $1x10^{-2}$ |
| | Pt-197 | | $1x10^{-3}$ |
| Potassium (19) | K-42 | | $3x10^{-3}$ |
| Praseodymium (59) | Pr-142 | | $3x10^{-4}$ |
| | Pr-143 | | $5x10^{-4}$ |
| Promethium (61) | Pm-147 | | $2x10^{-3}$ |
| | Pm-149 | | $4x10^{-4}$ |

| Element (atomic number) | ((~~Isotope~~)) Radionuclide | Column I Gas concentration µCi/ml[1] | Column II Liquid and solid concentration µCi/ml[2] |
|---|---|---|---|
| Radium (88) | Ra-226 | | $1x10^{-7}$ |
| | Ra-228 | | $3x10^{-7}$ |
| Rhenium (75) | Re-183 | | $6x10^{-3}$ |
| | Re-186 | | $9x10^{-4}$ |
| | Re-188 | | $6x10^{-4}$ |
| Rhodium (45) | Rh-103m | | $1x10^{-1}$ |
| | Rh-105 | | $1x10^{-3}$ |
| Rubidium (37) | Rb-86 | | $7x10^{-4}$ |
| Ruthenium (44) | Ru-97 | | $4x10^{-3}$ |
| | Ru-103 | | $8x10^{-4}$ |
| | Ru-105 | | $1x10^{-3}$ |
| | Ru-106 | | $1x10^{-4}$ |
| Samarium (62) | Sm-153 | | $8x10^{-4}$ |
| Scandium (21) | Sc-46 | | $4x10^{-4}$ |
| | Sc-47 | | $9x10^{-4}$ |
| | Sc-48 | | $3x10^{-4}$ |
| Selenium (34) | Se-75 | | $3x10^{-3}$ |
| Silicon (14) | Is-31 | | $9x10^{-3}$ |
| Silver (47) | Ag-105 | | $1x10^{-3}$ |
| | Ag-110m | | $3x10^{-4}$ |
| | Ag-111 | | $4x10^{-4}$ |
| Sodium (11) | Na-24 | | $2x10^{-3}$ |
| Strontium (38) | Sr-85 | | $1x10^{-3}$ |
| | Sr-89 | | $1x10^{-4}$ |
| | Sr-91 | | $7x10^{-4}$ |
| | Sr-92 | | $7x10^{-4}$ |
| Sulfur (16) | S-35 | $9x10^{-8}$ | $6x10^{-4}$ |
| Tantalum (73) | Ta-182 | | $4x10^{-4}$ |
| Technetium (43) | Tc-96m | | $1x10^{-1}$ |
| | Tc-96 | | $1x10^{-3}$ |
| Tellurium (52) | Te-125m | | $2x10^{-3}$ |
| | Te-127m | | $6x10^{-4}$ |
| | Te-127 | | $3x10^{-3}$ |
| | Te-129m | | $3x10^{-4}$ |
| | Te-131m | | $6x10^{-4}$ |
| | Te-132 | | $3x10^{-4}$ |
| Terbium (65) | Tb-160 | | $4x10^{-4}$ |
| Thallium (81) | Tl-200 | | $4x10^{-3}$ |
| | Tl-201 | | $3x10^{-3}$ |
| | Tl-202 | | $1x10^{-3}$ |
| | Tl-204 | | $1x10^{-3}$ |
| Thulium (69) | Tm-170 | | $5x10^{-4}$ |
| | Tm-171 | | $5x10^{-3}$ |
| Tin (50) | Sn-113 | | $9x10^{-4}$ |
| | Sn-125 | | $2x10^{-4}$ |

| Element (atomic number) | ((~~Isotope~~)) Radionuclide | Column I Gas concentration µCi/ml[1] | Column II Liquid and solid concentration µCi/ml[2] |
|---|---|---|---|
| Tungsten (Wolfram) (74) | W-181 | | $4x10^{-3}$ |
| | W-187 | | $7x10^{-4}$ |
| Vanadium (23) | V-48 | | $3x10^{-4}$ |
| Xenon (54) | Xe-131m | $4x10^{-6}$ | |
| | Xe-133 | $3x10^{-6}$ | |
| | Xe-135 | $1x10^{-6}$ | |
| Ytterbium (70) | Yb-175 | | $1x10^{-3}$ |
| Yttrium (39) | Y-90 | | $2x10^{-4}$ |
| | Y-91m | | $3x10^{-2}$ |
| | Y-91 | | $3x10^{-4}$ |
| | Y-92 | | $6x10^{-4}$ |
| | Y-93 | | $3x10^{-4}$ |
| Zinc (30) | Zn-65 | | $1x10^{-3}$ |
| | Zn-69m | | $7x10^{-4}$ |
| | Zn-69 | | $2x10^{-2}$ |
| Zirconium (40) | Zr-95 | | $6x10^{-4}$ |
| | Zr-97 | | $2x10^{-4}$ |
| Beta ((~~and/~~))or gamma emitting radioactive material not listed above with half-life less than 3 years | | $1x10^{-10}$ | $1x10^{-6}$ |

Notes: [1] Values are given in Column I only for those materials normally used as gases

[2] µCi/gm for solids

Note 1: Many ((~~radioisotopes disintegrate~~)) radionuclides decay into ((~~isotopes~~)) nuclides which are also radioactive. In expressing the concentrations in Schedule C the activity stated is that of the parent ((~~isotope~~)) nuclide and takes into account the daughters.

Note 2: For purposes of WAC 246-232-010(1) where there is involved a combination of ((~~isotopes~~)) nuclides, the limit for the combination should be derived as follows: Determine for each ((~~isotope~~)) nuclide in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific ((~~isotope~~)) nuclide when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

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

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.

REPEALER

The following section of the Washington Administrative Code is repealed:

| | |
|---|---|
| WAC 246-232-013 | Exemption of certain resins containing scandium-46 and designed for sand consolidation in oil wells. |