

Chapter 246-235 WAC

RADIOACTIVE MATERIALS—SPECIFIC LICENSES

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WAC

246-235-001 Purpose and scope.

FEEES

246-235-010 Filing application for specific licenses.

246-235-020 General requirements for the issuance of specific
licenses.

246-235-030 Issuance of specific licenses.

246-235-040 Expiration of licenses.

246-235-050 Renewal of license.

246-235-055 Precedence of license condition over regulation.

246-235-060 Amendment of licenses at request of licensee.

246-235-070 Agency action on applications to renew or amend.

246-235-075 Financial assurance and recordkeeping for
decommissioning.

246-235-077 Special requirements for emergency planning.

- 246-235-080 Special requirements for possession and use of medical calibration and reference sources.
- 246-235-082 Special requirements for issuance of a specific license to initially transfer source material.
- 246-235-083 Conditions of licenses to initially transfer source material for use under general license—Quality control, labeling, safety instructions, and reports and records.
- 246-235-084 Special requirements for issuance of specific licenses for industrial radiography.
- 246-235-085 Special requirements for issuance of a specific license for wireline services.
- 246-235-086 Special requirements for environmentally significant licensing actions.
- 246-235-090 Special requirements for specific licenses of broad scope.
- 246-235-091 Manufacture and distribution of industrial products containing depleted uranium under general license.

- 246-235-093 Manufacture, assembly or distribution of devices
under general license.
- 246-235-095 Manufacture, assembly, or distribution of luminous
safety devices, certain calibration sources or ice
detectors under general license.
- 246-235-097 Manufacture and distribution of radioactive
material for certain in vitro clinical or laboratory
testing under general license.
- 246-235-100 Manufacture, preparation, or transfer for
commercial distribution of radioactive drugs
containing radioactive material for medical use
under chapter 246-240 WAC.
- 246-235-102 Manufacture and distribution of sources or devices
containing radioactive material for medical use.
- 246-235-103 Prototype tests for manufacture of calibration or
reference sources containing americium-241 or
radium-226.

- 246-235-105 Manufacture, assembly or distribution of
radioactive material exempt from regulation.
- 246-235-107 Serialization of nationally tracked sources.
- 246-235-108 Sealed source and device registration and
inactivation.
- 246-235-110 Special requirements for issuance of specific
licenses for source material milling.
- 246-235-125 Special requirements to report transactions
involving nationally tracked sources.
- 246-235-130 Appendix-General laboratory rules for safe use of
unsealed sources.
- 246-235-140 Schedule B, limits for broad licenses.
- 246-235-150 Schedule C-Quantities of radioactive materials
requiring consideration of the need for an emergency
plan for responding to a release.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

- 246-235-120 Schedule A groups of medical uses of radioactive
material (ref. WAC 246-235-080(3) and 246-235-

100(9)). [Statutory Authority: RCW 70.98.050. WSR
98-13-037, § 246-235-120, filed 6/8/98, effective
7/9/98. Statutory Authority: RCW 70.98.050 and
70.98.080. WSR 91-15-112 (Order 184), § 246-235-120,
filed 7/24/91, effective 8/24/91. Statutory
Authority: RCW 43.70.040. WSR 91-02-049 (Order 121),
recodified as § 246-235-120, filed 12/27/90,
effective 1/31/91. Statutory Authority: RCW
70.98.080. WSR 87-01-031 (Order 2450), § 402-22-200,
filed 12/11/86. Statutory Authority: RCW 70.98.050.
WSR 81-01-011 (Order 1570), § 402-22-200, filed
12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-
12-073 (Order 1459), § 402-22-200, filed 11/30/79,
effective 1/1/80. Formerly WAC 402-20-260.] Repealed
by WSR 06-05-019, filed 2/6/06, effective 3/9/06.
Statutory Authority: RCW 70.98.050.

WAC 246-235-001 Purpose and scope. (1) This chapter establishes requirements for the issuance of specific licenses.

(2) The provisions and requirements of this chapter are in addition to, and not in substitution for, other requirements of these regulations. In particular the provisions of chapter 246-232 WAC apply to applications and licenses subject to this chapter.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-001, filed 2/23/15, effective 3/26/15. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-001, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-001, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-010, filed 11/30/79, effective 1/1/80. Formerly chapter 402-20 WAC.]

FEEES

WAC 246-235-010 Filing application for specific licenses.

(1) An applicant applying for a specific license shall submit an application on a department approved form.

(2) The department may at any time after the filing of the original application, and before the expiration of the license,

require further statements in order to enable the department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

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

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

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

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

(ii) Contain the information identified in WAC 246-235-108(3).

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

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

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such

information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

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

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

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

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

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

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

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

(c) Identification of individuals authorized to prepare the positron emission tomography radioactive drugs if the applicant

is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in WAC 246-235-100 (2) (b).

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-010, filed 9/20/22, effective 10/21/22.

Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-010, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-010, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-010, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-010, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050

and 70.98.080. WSR 09-06-003, § 246-235-010, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-020, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-050.]

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

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

(2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and safety and minimize danger to life or property;

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

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

(5) The applicant satisfies any applicable special requirements in chapters 246-220 through 246-254 WAC; and

(6) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, uranium enrichment facility construction and operation, production of uranium hexafluoride, or for the conduct of any other activity which the department determines will significantly affect the quality of the environment, the applicant may not begin construction until the department has weighed the environmental, economic, technical, and other benefits against the environmental costs, and, considering available alternatives, has concluded that the issuance of the license is appropriate, with any appropriate conditions to protect environmental values. Commencement of construction prior to approval by the department shall be

grounds for denial of a license to receive and possess radioactive material in the plant or facility. Commencement of construction as defined in chapter 246-220 WAC may include nonconstruction activities if the activity has a reasonable nexus to radiological safety and security.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-020, filed 9/20/22, effective 10/21/22.

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

WAC 246-235-030 Issuance of specific licenses. (1) Upon a determination that an application meets the requirements of the act and the regulations of the department the department will

issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, storage, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or theft of material subject to this part. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-030, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-045, filed 12/11/86; WSR 79-12-073 (Order 1459), § 402-22-045, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-080.]

WAC 246-235-040 Expiration of licenses. Except as provided in WAC 246-235-050(2), each specific license expires at the end of the day, in the month and year stated therein.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-040, filed 2/23/15, effective 3/26/15. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-040, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-050, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-100.]

WAC 246-235-050 Renewal of license. (1) Applications for renewal of specific licenses shall be filed in accordance with WAC 246-235-010.

(2) In any case in which a licensee, not less than thirty days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the department.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-050, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-050, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-055, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-110.]

WAC 246-235-055 Precedence of license condition over regulation. (1) A license condition may be used to specifically modify any regulation pertaining to the possession, use, storage, transfer, or disposal of radioactive material. Any license condition used to modify an existing regulation must set forth the title, chapter, section, and, where applicable, any subsection and paragraph numbers for the regulation being modified, and fully define the nature and extent of the modification.

(2) In the event a regulation is changed, an existing license condition that is more restrictive than the new regulation remains in force until there is an amendment or renewal of the license that removes or modifies the license condition.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-055, filed 2/23/15, effective 3/26/15; WSR 94-01-073, § 246-235-055, filed 12/9/93, effective 1/9/94.]

WAC 246-235-060 Amendment of licenses at request of

licensee. Applications for amendment of a license must be filed in accordance with WAC 246-235-010 and must specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-060, filed 2/23/15, effective 3/26/15. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-060, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-060, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-22-060, filed 9/16/83; WSR 79-12-073 (Order 1459), § 402-22-060, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-120.]

WAC 246-235-070 Agency action on applications to renew or

amend. In considering an application by a licensee to renew or amend the license, the department will apply the criteria set forth in this chapter, as applicable.

[Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-070, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-065, filed 12/11/86; WSR 79-12-073 (Order 1459), § 402-22-065, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-130.]

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 120 days and in quantities for unsealed material exceeding 10^3 times and for sealed forms exceeding 10^{10} times the applicable quantities set

forth in WAC 246-221-300 Appendix B (for a combination of nuclides the unity rule applies. A decommissioning funding plan will be required if R is greater than 1, where R is defined as the sum of the ratios of the quantity for sealed and unsealed forms of each nuclide compared to the applicable value derived from WAC 246-221-300).

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

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

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

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

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

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

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

(iii) Any previous spills of radioactive material;

(iv) An adequate contingency factor;

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

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

(vii) Anticipated waste volume;

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

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

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

(xi) On-site disposal; and

(xii) Use of settling or evaporation ponds.

(d) A description of the method of assuring funds for decommissioning, pursuant to subsection (4) of this section, including means for adjusting levels periodically over the life of the facility or facilities.

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

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

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

(4) Each applicant shall submit a certification that financial assurance for decommissioning meets the amount of the approved decommissioning cost estimate prior to commencement of

the use of any radioactive materials. The applicant or licensee shall provide a signed original of the financial instrument obtained to satisfy the financial surety requirement unless a previously submitted and accepted financial instrument continues to cover the plan and cost estimate for decommissioning. That financial instrument must be one or more of the following approved methods:

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

(b) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. Any

surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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

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

government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

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

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

(d) Statement of intent. In the case of state or local government licensees, a statement of intent containing a cost

estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

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

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

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

decommissioning funding plan. It must specifically address the effect of the following events on decommissioning costs:

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

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

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

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

(6) Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with WAC 246-232-050(2), licensees shall transfer all records described

in this subsection to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated by the department. If records of relevant information are kept for other purposes, reference to these records and their locations may be used.

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

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

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

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

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

any known information on identification of involved nuclides, quantities, forms, and concentrations.

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

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

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

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

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-075, filed 9/20/22, effective 10/21/22.

Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-075, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-075, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.095 and 70.98.050. WSR 07-03-049, § 246-235-075, filed 1/12/07, effective 2/12/07. Statutory Authority: RCW 70.98.050. WSR 00-07-085, § 246-235-075, filed 3/15/00, effective 4/15/00;

WSR 99-15-105, § 246-235-075, filed 7/21/99, effective 8/21/99.
Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 97-08-095,
§ 246-235-075, filed 4/2/97, effective 5/3/97; WSR 92-06-008
(Order 245), § 246-235-075, filed 2/21/92, effective 3/23/92.]

WAC 246-235-077 Special requirements for emergency

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

(a) An evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(b) An emergency plan for responding to a release of radioactive material.

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

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

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

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

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

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

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

(g) Other factors appropriate for the specific facility.

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

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

(b) Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

(c) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(d) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(e) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment.

(f) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(g) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly

notifying off-site response organizations and the department;
also responsibilities for developing, maintaining, and updating
the plan.

(h) Notification and coordination. A commitment to and a
brief description of the means to promptly notify off-site
response organizations and request off-site assistance,
including medical assistance for the treatment of contaminated
injured on-site workers when appropriate. A control point must
be established. The notification and coordination must be
planned so that unavailability of some personnel, parts of the
facility, and some equipment will not prevent the notification
and coordination. The licensee must also commit to notify the
department immediately after notification of the appropriate
off-site response organizations and not later than one hour
after the licensee declares an emergency. These reporting
requirements do not supersede or release licensees from
complying with the requirements under the Emergency Planning and
Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499
or other state or federal reporting requirements.

(i) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the department.

(j) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(k) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(l) Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and

biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site, and the scenarios must not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

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

activities at the proposed place of use of the radioactive material.

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-077, filed 9/20/22, effective 10/21/22.

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

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

(a) Any licensee or registrant who possesses sealed sources as calibration or reference sources must test for leakage or contamination each sealed source containing radioactive material, other than Hydrogen-3, with a half-life greater than

30 days in any form other than gas at least every six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed sources must not be used until tested. However, leak tests are not required when: The source contains 3.7 megabecquerels (100 microcuries) or less of beta or gamma emitting material or 370 kilobecquerels (10 microcuries) or less of alpha emitting material or the sealed source is stored and is not being used: Provided, a physical inventory of the source and wipe surveys of the storage area or storage container are conducted as required by these rules or license condition.

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

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

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

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

kinds of radioactive material, location of sources, name of person performing the inventory, and the date of the inventory. [Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-080, filed 9/20/22, effective 10/21/22. Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-080, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-080, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-080, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 06-05-019, § 246-235-080, filed 2/6/06, effective 3/9/06; WSR 00-08-013, § 246-235-080, filed 3/24/00, effective 4/24/00; WSR 98-13-037, § 246-235-080, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-080, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-070, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-22-070, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-22-070, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-070, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-070.]

WAC 246-235-082 Special requirements for issuance of a specific license to initially transfer source material. In

addition to the requirements set forth in WAC 246-235-020, an application for a specific license to initially transfer source material for use under 10 C.F.R. 40.22 or WAC 246-233-010 or equivalent regulations of an agreement state will be approved if:

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

(2) The applicant submits adequate information about, and the department approves, the methods to be used for quality control, labeling, and providing safety instructions to recipients.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-235-082, filed 6/10/16, effective 7/11/16.]

WAC 246-235-083 Conditions of licenses to initially transfer source material for use under general license—Quality control, labeling, safety instructions, and reports and records.

(1) Each person licensed under WAC 246-235-082 shall label the immediate container of each quantity of source material with the

type and quantity of source material and the words "radioactive material."

(2) Each person licensed under WAC 246-235-082 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(3) Each person licensed under WAC 246-235-082 shall provide the information specified in this section to each person to whom source material is transferred for use under WAC 246-233-010, 10 C.F.R. 40.22, or equivalent provisions in agreement state regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of 10 C.F.R. 40.22 and 10 C.F.R. 40.51, or WAC 246-232-080 and 246-233-010, or equivalent agreement state regulations.

(b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(4) Each person licensed under WAC 246-235-082 shall report transfers as follows:

(a) File a report with the director, Office of Radiation Protection, Radioactive Materials Section, P.O. Box 47827, Olympia, WA 98504. The report shall include the following information:

(i) The name, address, and license number of the person who transferred the source material;

(ii) For each general licensee under these rules, 10 C.F.R. 40.22, or equivalent agreement state regulations, to whom greater than 50 grams (0.11 lbs.) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible agency, agreement state, or NRC, that identifies all persons, operating under provisions of 10 C.F.R. 40.22 or equivalent regulations of the department or an agreement state, to whom greater than 50 grams (0.11 lbs.) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state being reported to:

(i) The name, address, and license number of the person who transferred the source material;

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state.

(c) Submit each report by January 31st of each year covering all transfers for the previous calendar year. If no

transfers were made to persons generally licensed under 10 C.F.R. 40.22 or equivalent department rules or agreement state regulations during the current period, a report shall be submitted to the department so indicating. If no transfers have been made to general licensees in a particular state during the reporting period, this information shall be reported to the responsible agency upon request by the agency.

(5) Each person licensed under 10 C.F.R. 40.54 or equivalent department or agreement state regulations shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the department, NRC, or to an agreement state agency.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-083, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-083, filed 6/10/16, effective 7/11/16.]

WAC 246-235-084 Special requirements for issuance of specific licenses for industrial radiography. In addition to the requirements set forth in WAC 246-235-020, a specific

license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of WAC 246-243-050 and 246-243-130.

(a) After June 30, 2000, a license applicant need not describe its initial training and examination program for radiographers in the subjects outlined in WAC 246-243-230.

(b) From June 30, 2000, to January 1, 2001, a license applicant may affirm that all individuals acting as industrial radiographers will be certified in radiation safety by a certifying entity before beginning duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in WAC 246-243-230.

(2) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(3) The applicant submits written operating and emergency procedures as described in WAC 246-243-140.

(4) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed six months as described in WAC 246-243-050.

(5) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(6) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (WAC 246-243-047) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(7) If an applicant intends to perform leak testing of sealed sources or of exposure devices containing depleted uranium shielding, the applicant shall describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to

analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

- (a) Instruments to be used;
- (b) Methods of performing the analysis; and
- (c) Pertinent experience of the person who will analyze the wipe samples.

(8) If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to these procedures and the intervals prescribed in WAC 246-243-080.

(9) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(10) The applicant identifies the location where all records required by this section and other sections of these regulations will be maintained.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-084, filed 2/23/15, effective 3/26/15; WSR 00-08-013, § 246-235-084, filed 3/24/00, effective 4/24/00.]

WAC 246-235-085 Special requirements for issuance of a specific license for wireline services. In addition to the requirements set forth in this chapter, a specific license for use of radioactive material in wireline services must be issued if:

(1) The applicant satisfies the applicable requirements in chapter 246-244 WAC and any special requirements contained in this chapter.

(2) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the department a description of this program which specifies:

(a) Initial training;

(b) On-the-job training;

(c) Annual safety reviews provided by the licensee;

(d) Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of, and ability to comply with, the department's rules and licensing requirements and the applicant's operating and emergency procedures; and

(e) Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of, and ability to comply with, the applicant's operating and emergency procedures.

(3) The applicant shall submit to the department written operating and emergency procedures as described in WAC 246-244-150 or an outline or summary of the procedures which includes the important radiation safety aspects of the procedures.

(4) The applicant shall establish and submit to the department its program for annual inspections of the job performance of each logging supervisor to ensure the department's rules, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for at least three years after each annual internal inspection.

(5) The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in wireline services, including specified delegations of authority and responsibility.

(6) If an applicant wants to perform their own leak testing of their own sealed sources, the applicant shall identify the

manufacturers and the model number(s) of the leak test kits to be used. If the applicant wants to analyze its own leak test samples, the applicant shall establish procedures to be followed and submit a description of the procedures to the department.

This description must include:

- (a) Instruments to be used;
- (b) Methods of performing the analysis;
- (c) Sample calculation and sample leak test report forms;

and

- (d) Pertinent experience of the person who will analyze the wipe samples.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-085, filed 2/23/15, effective 3/26/15.]

WAC 246-235-086 Special requirements for environmentally significant licensing actions. In addition to the requirements set forth in WAC 246-235-020, a specific license for any activity within the licensing authority of the department which the department determines will significantly affect the radiological quality of the human environment, including those

specified in WAC 197-11-845(1) and 246-03-030 (1)(a)(ii) (i.e., licenses to operate low level waste burial facilities or licenses to operate or expand beyond the design capacity, mineral processing facilities or their tailings areas, whose products, or by-products, have concentrations of naturally occurring radioactive material in excess of exempt concentrations as specified in WAC 246-232-130, Schedule C), will be issued if the following conditions are met:

(1) Environmental impact statement.

(a) The application for a license or license amendment (other than administrative amendments) is accompanied or preceded by a final environmental impact statement or final declaration of nonsignificance completed in accordance with the SEPA procedures and guidelines specified in chapters 197-11 and 246-03 WAC. For any uranium or thorium mill in operation on or before the effective date of this regulation for which an environmental impact statement has not been prepared previously, an application for license renewal must be accompanied or preceded by a final environmental impact statement or final declaration of nonsignificance completed in accordance with SEPA

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

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

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

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

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

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

(2) For uranium or thorium milling operations, a bond made payable to the department of health or other acceptable government agency, and in an amount specified by the department, must be posted to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements for reclamation and disposal of tailings and for decommissioning the site. The bond,

or a copy thereof when the bond is made payable to another government agency, must be received by the department prior to issuance of the license, or prior to license renewal for mills in operation on or before the effective date of this regulation. Other acceptable surety arrangements in addition to surety bonding include cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit or combinations of the foregoing. The amount and mechanism of the surety arrangement may be reviewed by the department preceding each license renewal and adjustments may be required of the licensee prior to such renewal.

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

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

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

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

(6) All licensees or registrants required to meet the additional requirements set forth in this subsection shall establish environmental monitoring programs adequate to determine the impact of their activity on the natural

environment around the site of their environmentally significant activity. The established environmental and effluent monitoring program must address all environmentally significant radionuclide releases and external radiation sources caused or threatened to be caused by the licensee's activities.

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

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

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

(A) Chemical composition;

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

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

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

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

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

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

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

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

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

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

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

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

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

be reported in a manner which will allow the department to confirm the potential annual radiation doses to the public.

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-086, filed 9/20/22, effective 10/21/22.

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

WAC 246-235-090 Special requirements for specific licenses of broad scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of these licenses. A person may not introduce radioactive material into a product or material, knowing or having reasons to believe that it will be transferred to persons exempt under this section or other sections or equivalent regulations of the NRC or an agreement state, except in

accordance with a specific license issued by the NRC, Washington, D.C. 20555. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity or other product containing source material, by-product material or radioactive material, whose subsequent possession, use, transfer and disposal by all other persons exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

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

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

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 246-235-140 Schedule B,

for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in WAC 246-235-140 Schedule B, Column I. If two or more radionuclides are possessed, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in WAC 246-235-140 Schedule B, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in WAC 246-235-140 Schedule B, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in WAC 246-235-140 Schedule B, Column II. If two or more radionuclides are possessed, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the

quantity possessed to the applicable quantity specified in WAC 246-235-140 Schedule B, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

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

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

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

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

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

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

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

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

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the 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 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material,

procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

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

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

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

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

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

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

(b) For each Type A specific license of broad scope radioactive material possessed under the license may only be

used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-090, filed 9/20/22, effective 10/21/22.

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

RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-090, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-073.]

WAC 246-235-091 Manufacture and distribution of industrial products containing depleted uranium under general license. (1)

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

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

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

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide 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 manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

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

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

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

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

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

(e) Report to the department all transfers of industrial products or devices to persons for use under the general license in WAC 246-233-010(4). Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed

person. If no transfers have been made to persons generally licensed under chapter 246-233 WAC during the reporting period, the report must so indicate;

(f) Provide certain other reports as follows:

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

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

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

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

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-091, filed 9/20/22, effective 10/21/22.

Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-091, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-

091, filed 11/22/13, effective 12/23/13; WSR 98-13-037, § 246-235-091, filed 6/8/98, effective 7/9/98.]

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

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

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

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

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

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

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

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

(i) Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents

such as operating and service manuals may be identified in the label and used to provide this information);

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

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

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

CAUTION - RADIOACTIVE MATERIAL

.....
Name of manufacturer or distributor

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

CAUTION - RADIOACTIVE MATERIAL

.....
Name of manufacturer or distributor

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

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

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

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

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval

for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

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

similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under WAC 246-233-020, or under equivalent regulations of the NRC or an agreement state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application

written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive in one year a radiation dose in excess of 10 percent of the limits specified in the table in WAC 246-221-010(1).

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

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

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

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

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

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

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

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

(i) A copy of the appropriate NRC or an agreement state's regulations, equivalent to WAC 246-233-020, 246-232-050, 246-

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

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

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

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

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

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

general license in WAC 246-233-020 and all receipts of devices from persons licensed under WAC 246-233-020.

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

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

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

(C) The date of transfer;

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

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

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the 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 a general licensee under WAC 246-233-020, the report must include:

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

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

(C) The date of receipt; and

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

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

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

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

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

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

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

233-020 and all receipts of devices from persons licensed under regulations equivalent to WAC 246-233-020.

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

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

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

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and

authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

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

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

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

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

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

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

(C) The date of receipt; and

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

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

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

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

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

(x) If no transfers have been made to or from general licensees within an agreement state during the reporting period,

this information must be reported to the responsible agreement state agency upon request of the agency.

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-093, filed 9/20/22, effective 10/21/22.

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

WAC 246-235-095 Manufacture, assembly, or distribution of luminous safety devices, certain calibration sources or ice detectors under general license. (1) *Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft.* An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under WAC 246-233-025 will be approved subject to the following conditions:

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

(b) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 C.F.R. Part 32 or their equivalent.

(2) *Special requirements for license to manufacture calibration sources containing americium-241 or radium-226 for distribution to persons generally licensed under WAC 246-233-035.* An application for a specific license to manufacture calibration and reference sources containing americium-241 or

radium-226 to persons generally licensed under WAC 246-233-035 will be approved subject to the following conditions:

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

(b) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 C.F.R. Part 32 and Section 70.39 of 10 C.F.R. Part 70 or their equivalent.

(3) *Licensing the manufacture and distribution of ice detection devices.* An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under WAC 246-233-030 will be approved subject to the following conditions:

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

(b) The criteria of Sections 32.61 and 32.62 of 10 C.F.R. Part 32 are met.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-235-095, filed 12/12/16, effective 1/12/17; WSR 16-13-054, § 246-235-095, filed 6/10/16, effective 7/11/16.
Statutory Authority: RCW 70.98.050. WSR 04-04-055, § 246-235-

095, filed 1/30/04, effective 3/1/04; WSR 98-13-037, § 246-235-095, filed 6/8/98, effective 7/9/98.]

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, acquisition, possession, use and transfer are subject to the regulations and a general license of the NRC or of a state with which the 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 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 in WAC 246-221-170 of these rules.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-235-097, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-097, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050.

WSR 04-04-055, § 246-235-097, filed 1/30/04, effective 3/1/04;
WSR 98-13-037, § 246-235-097, filed 6/8/98, effective 7/9/98.]

**WAC 246-235-100 Manufacture, preparation, or transfer for
commercial distribution of radioactive drugs containing
radioactive material for medical use under chapter 246-240 WAC.**

(1) An application for a specific license to manufacture,
prepare, or transfer for commercial distribution radioactive
drugs containing radioactive material for use by persons
authorized pursuant to chapter 246-240 WAC will be approved if:

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

(b) The applicant submits evidence of at least one of the
following:

(i) Is registered with the United States Food and Drug
Administration as the owner or operator of a drug establishment
that engages in the manufacture, preparation, propagation,
compounding, or processing of a drug under 21 C.F.R. Part 207,
Subpart B;

(ii) Is registered or licensed with the pharmacy quality assurance commission as a drug manufacturer;

(iii) Is licensed as a pharmacy by the pharmacy quality assurance commission;

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

(v) Is a positron emission tomography drug production facility registered with the Washington state pharmacy quality assurance commission.

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

(d) The applicant commits to the following labeling requirements:

(i) 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 100 days, the time may be omitted.

(ii) 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 ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee who is licensed as a pharmacy by the Washington state pharmacy quality assurance commission, or who is operating as a nuclear pharmacy within a federal medical institution:

(a) May prepare radioactive drugs for medical use, as defined in WAC 246-240-010, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as

specified in (b) and (d) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist as specified in WAC 246-240-057.

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

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

(ii) This individual meets the requirements of WAC 246-240-081 and 246-240-075(2); and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

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

(d) May designate a pharmacist, as defined in WAC 246-240-010, as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

(ii) The individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at any other pharmacies before August 8, 2009.

(e) Must provide to the department:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the NRC or an agreement state as specified in WAC 246-240-075(1); or

(ii) The NRC or agreement state license; or

(iii) The NRC master materials licensee permit; or

(iv) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian

tribe before November 30, 2007, or at all other locations of use before August 8, 2009; and

(vi) A copy of the Washington state pharmacy license or registration, no later than 30 days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist under (b)(i) or (iii) of this subsection.

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

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

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

(4) A licensee must satisfy the labeling requirements in subsection (1)(d) of this section.

(5) Nothing in this section relieves the licensee from complying with applicable United States Food and Drug Administration requirements, other federal requirements, and state requirements governing radioactive drugs.

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-100, filed 9/20/22, effective 10/21/22.

Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-100, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-100, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-100, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 07-14-131, § 246-235-100, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-235-100, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-235-100, filed 6/8/98, effective 7/9/98.

Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-100, filed 7/24/91, effective 8/24/91.

Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-100, filed 12/27/90, effective 1/31/91.

Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-22-110, filed 12/8/80. Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-110, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-076.]

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 devices 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 NRC or an agreement 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) The source or device has been registered in the sealed source and device registry.

(5) 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.

(6) 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.

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 16-13-054, § 246-235-102, filed 6/10/16, effective 7/11/16. Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-235-102, filed 11/22/13, effective 12/23/13; WSR 07-14-131, § 246-235-102, filed 7/3/07, effective 8/3/07; WSR 06-05-019, § 246-235-102, filed 2/6/06, effective 3/9/06; WSR 98-13-037, § 246-235-102, filed 6/8/98, effective 7/9/98.]

**WAC 246-235-103 Prototype tests for manufacture of
calibration or reference sources containing americium-241 or
radium-226.** An applicant for a license under this chapter

shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of no less than five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

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

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

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

dried or by direct measurement of the radioactivity remaining on the source following the wet wipe.

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

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-103, filed 9/20/22, effective 10/21/22.

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

WAC 246-235-105 Manufacture, assembly or distribution of radioactive material exempt from regulation. 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.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-235-105, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-105, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 01-02-067, § 246-235-105, filed 12/29/00, effective 1/29/01; WSR 98-13-037, § 246-235-105, filed 6/8/98, effective 7/9/98.]

WAC 246-235-107 Serialization of nationally tracked

sources. Each licensee who manufactures a nationally tracked source after February 6, 2007, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-107, filed 2/18/09, effective 3/21/09.]

WAC 246-235-108 Sealed source and device registration and

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

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

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the

request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

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

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

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

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

(b) The provisions of the registration certificate.

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

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

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

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

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

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

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

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more

than 740 gigabecquerels (20 curies) of tritium (H-3) or 7.4 gigabecquerels (200 millicuries) of any other radionuclide.

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

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

transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

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

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

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-19-084, § 246-235-108, filed 9/20/22, effective 10/21/22.

Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034,

§ 246-235-108, filed 12/12/16, effective 1/12/17; WSR 16-13-054,
§ 246-235-108, filed 6/10/16, effective 7/11/16.]

WAC 246-235-110 Special requirements for issuance of specific licenses for source material milling. In addition to the requirements set forth in WAC 246-235-020, the department will issue a specific license for source material milling when the applicant submits a satisfactory application and meets the other conditions specified below:

(1) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material as defined in WAC 246-220-010 must address the following:

- (a) Description of the proposed project or action.
- (b) Area/site characteristics including geology, demography, topography, hydrology and meteorology.
- (c) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts.
- (d) Environmental effects of accidents.

(e) Tailings disposal and decommissioning.

(f) Site and project alternatives.

(g) Description of how the provisions of chapter 246-252 WAC must be met.

(2) Under WAC 246-235-086, the applicant shall not commence construction of the project until the department has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(3) Prior to issuance of a license, the department shall hold a public hearing. The hearing will address the adequacy of the reclamation, disposal, decommissioning, and decontamination plans.

(4) At least one full year prior to any major site construction, a preoperational monitoring program must be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program must be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control

systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(5) Prior to issuance of the license, the mill operator shall establish financial surety arrangements consistent with WAC 246-252-030.

(6) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(a) Milling operations must be conducted so that all effluent releases are reduced to as low as reasonably achievable below the limits of chapter 246-221 WAC.

(b) The mill operator shall conduct at least a daily inspection of any tailings or waste retention systems. Records of these inspections must be maintained for review by the department.

(c) The mill operator shall immediately notify the department of:

(i) Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas; and

(ii) Any unusual conditions (conditions not contemplated in the design of the retention system) which if not corrected could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(7) An application for a license to own, receive, possess and use by-product material as defined in WAC 246-220-010 must contain proposed specifications relating to the emissions control and disposition of the by-product material to achieve the requirements and objectives set forth in the criteria listed in WAC 246-252-030.

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-110, filed 2/23/15, effective 3/26/15; WSR 06-05-019, § 246-235-110, filed 2/6/06, effective 3/9/06. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-110, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-110, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-150, filed 12/11/86. Statutory Authority: Chapter 70.121 RCW. WSR 81-16-031 (Order 1683), § 402-22-150, filed 7/28/81.]

WAC 246-235-125 Special requirements to report

transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subsections (1) through (5) of this section for each type of transaction.

(1) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information;

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source;

(d) The radioactive material in the source;

(e) The initial source strength in becquerels (curies) at the time of manufacture; and

(f) The manufacture date of the source.

(2) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name and license number of the recipient facility and the shipping address;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The shipping date;

(i) The estimated arrival date; and

(j) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste

manifest number and the container identification of the container with the nationally tracked source.

(3) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The name, address, and license number of the person that provided the source;

(d) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(e) The radioactive material in the source;

(f) The initial or current source strength in becquerels (curies);

(g) The date for which the source strength is reported;

(h) The date of receipt; and

(i) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(4) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the source;

(e) The initial or current source strength in becquerels (curies);

(f) The date for which the source strength is reported; and

(g) The disassemble date of the source.

(5) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking

Transaction Report. The report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The waste manifest number;

(d) The container identification with the nationally tracked source;

(e) The date of disposal; and

(f) The method of disposal.

(6) The reports discussed in subsections (1) through (5) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(a) The online National Source Tracking System;

(b) Electronically using a computer-readable format;

(c) By facsimile;

(d) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(e) By telephone with follow-up by facsimile or mail.

(7) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections (1) through (5) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(8) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1

nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 9, 2009. The information may be submitted by using any of the methods identified by subsection (7)(a) through (d) of this section. The initial inventory report must include the following information:

(a) The name, address, and license number of the reporting licensee;

(b) The name of the individual preparing the report;

(c) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(d) The radioactive material in the sealed source;

(e) The initial or current source strength in becquerels (curies); and

(f) The date for which the source strength is reported.

Table 1 - Nationally Tracked Source Thresholds

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
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Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-125, filed 2/18/09, effective 3/21/09.]

WAC 246-235-130 Appendix—General laboratory rules for safe use of unsealed sources. (1) In addition to the requirements in WAC 246-235-020, a specific licensee who uses unsealed, unplated 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 in accordance with, but not limited to, the following:

(a) Receive, handle, and store radioactive material 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, OSL, or TLD), when required, at all times when working with, or in the vicinity of, radioactive materials. Extremity doses must be considered 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, must be stored only in a designated low-background area. Calculations based on 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, 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 must not be worn outside the immediate work area.

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

[Statutory Authority: RCW 70.98.050. WSR 15-06-015, § 246-235-130, filed 2/23/15, effective 3/26/15; WSR 13-24-025, § 246-235-130, filed 11/22/13, effective 12/23/13; WSR 94-01-073, § 246-235-130, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-130, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-130, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-22-240, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-22-240, filed 9/16/83.]

WAC 246-235-140 Schedule B, limits for broad licenses.

(See also WAC 246-235-090)

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.

Radioactive Material	Col. I curies	Col. II curies
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-112 (Order 184), § 246-235-140, filed 7/24/91, effective 8/24/91.
Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-235-140, filed 12/27/90, effective 1/31/91.
Statutory Authority: RCW 70.98.080. WSR 79-12-073 (Order 1459), § 402-22-250, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-270.]

WAC 246-235-150 Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material ¹	Release fraction	Possession limit (curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000

Radioactive material ¹	Release fraction	Possession limit (curies)
Californium-252 ²	.001	9
Carbon-14 ³	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100

Radioactive material ¹	Release fraction	Possession limit (curies)
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	0.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Uranium Hexafluoride	.001	Note ⁴
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000

Radioactive material ¹	Release fraction	Possession limit (curies)
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma ⁵	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha ⁵	.0001	20
Combinations of radioactive materials listed above ¹		

¹ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

² For Californium-252, the quantity may also be expressed as 20 milligrams.

³ Excludes Carbon-14 as carbon dioxide.

⁴ For uranium hexafluoride, the quantity is 50 kilograms in a single container or 1,000 kilograms total.

⁵ Waste packaged in Type B containers does not require an emergency plan.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-150, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 95-01-108, § 246-235-150, filed 12/21/94, effective 1/21/95.]