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To: "NRC-JPiccone (E-mail)" <JMP1@nrc.gov>, "jgz@nrc.gov" <jgz@nrc.gov>
Date: 2/9/04 6:06PM
Subject: Submittal of final rules to meet RATS 2001-1

Josephine M Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Piccone:

Attached are files containing the pertinent sections of the Washington Administrative Code filed for final adoption on January 30, 2004. The proposed revisions were made available for public comment on December 17 as Washington State Register number WSR 03-23-133 with a request for comments by the public hearing date of January 6, 2004. The proposed regulations are identified by line-in/line-out text and correspond to the following equivalent amendments to NRC's regulations identified in RATS ID 2001-1):

10 CFR	WAC 246-
30.31	232-020
30.34	232-050
31.1	233-001
21.2	233-020
31.5	233-020
32.51	235-093
31.51a	235-093
31.52	235-093

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 360-236-3213 or by return e-mail.

Sincerely,

Terry C. Frazee, Western Regional Director

<<246-254rev2.rtf>> <<246-232rev2.rtf>> <<246-233rev2.rtf>>
<<246-235rev2.rtf>> <<246-239-080rev2.rtf>>

Public Health - Always Working for a Safer and Healthier Washington

This message from Terry C. Frazee
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Quick ways to reach me:
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AMENDATORY SECTION (Amending WSR 03-14-034, filed 6/23/03, effective 7/24/03)

WAC 246-254-090 Fees for industrial radioactive material licenses.

(1) Persons licensed or authorized to possess or use radioactive material in the following industrial categories shall forward annual fees to the department as follows:

(a) Five thousand five hundred thirty-five dollars for a license authorizing the use of radiographic exposure devices in one or more permanent radiographic vaults in a single facility.

(b) Seven thousand four hundred fifteen dollars for a license authorizing the use of radiographic exposure devices at temporary job sites but operating from a single storage facility.

(c) Three thousand six hundred thirty-five dollars for a license authorizing well-logging activities including the use of radioactive tracers operating from a single storage facility.

(d) Seven hundred eighty-five dollars for a license authorizing possession of portable sealed sources including moisture/density gauges and excluding radiographic exposure devices operating from a single storage facility.

(e) Eight hundred sixty dollars for a license authorizing possession of any nonportable sealed source, including special nuclear material and excluding radioactive material used in a gas chromatograph at a single facility.

(f) Five hundred forty dollars for a license authorizing possession of gas chromatograph units containing radioactive material at a single facility.

(g) One thousand four hundred ninety-five dollars for a license authorizing possession of any self-shielded or pool type irradiator with sealed source total quantity greater than one hundred curies at a single facility.

(h) Seven thousand nine hundred thirty dollars for a license authorizing possession of sealed sources for a walk-in type irradiator at a single facility.

(i) Six thousand nine hundred dollars for a license authorizing possession of greater than one gram of unsealed special nuclear material or greater than five hundred kilograms of source material at a single facility.

(j) Two thousand two hundred ten dollars for a license authorizing possession of less than or equal to one gram of unsealed special nuclear material or five hundred kilograms of source material at a single facility.

(k) Three hundred fifty dollars for a license authorizing possession of static elimination devices not covered by a general license.

(2) Persons with licenses authorizing multiple locations of permanent storage shall increase the annual fee by fifty percent for each additional location.

(3) Depleted uranium registrants required to file Form RHF-20 shall forward an annual fee of seventy-two dollars to the department.

(4) General licensees required to register in accordance with WAC 246-233-020 (3)(k) shall forward an annual fee of two hundred fourteen dollars to the department.

Deleted: fifteen

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

WAC 246-232-020 Types of licenses. Licenses for radioactive materials are of two types: General and specific.

(1) General licenses provided in chapter 246-233 WAC are effective without the filing of applications with the department or the issuance of licensing documents to the particular persons, although registration or the filing of a certificate with the department may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

(2) Specific licenses require the submission of an application to the department and the issuance of a licensing document by the department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document. (See chapter 246-235 WAC.)

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

WAC 246-232-040 Reciprocal recognition of licenses. (1) Subject to these regulations, any person who holds a specific license from the United States Nuclear Regulatory Commission or any agreement state or licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty days in that twelve month period which commences the date approval is granted, and the appropriate fee received, by the department provided that:

(a) The licensing document does not limit the activity authorized by such document to specified installations or locations;

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

(c) The out-of-state licensee notifies the department in writing and pays or has paid the appropriate fee (refer to chapter 246-254 WAC), at least three days prior to each entry to the state to engage in such activity. The written notification must be sent to the Radioactive Materials Section, Department of Health, Mailstop 47827, Olympia, Washington 98504-7827 and the fee should be sent to Washington State Department of Health, Revenue Accounting, P.O. Box 1099, Olympia, Washington 98504. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by copies of the pertinent licensing documents. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon telephone application to the department (360 236-3220), obtain permission to proceed sooner. The department may waive the requirement for filing additional written notifications during the remainder of the twelve months following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection;

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

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

(f) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person:

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

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

(2) Notwithstanding the provisions of subsection (1) of this section, any person who holds a specific license issued by the United States Nuclear Regulatory Commission, an agreement state or a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in WAC 246-233-020(~~(+4)~~) within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service a device in this state in areas not under exclusive federal jurisdiction provided that:

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

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the United States Nuclear Regulatory Commission, an agreement state or a licensing state;

(c) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(d) The holder of the specific license shall furnish to each general licensee to whom such device is transferred or on whose premises such device is installed a copy of the general license contained in WAC 246-233-020(4).

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

AMENDATORY SECTION (Amending Order 245, filed 2/21/92, effective 3/23/92)

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

(2) No license issued or granted under chapters 246-233 and 246-235 WAC and no right to possess or utilize radioactive material granted by any license issued pursuant to chapters 246-233 and 246-235 WAC shall be transferred, assigned, or in any manner disposed, either voluntarily or

involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.

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

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

(5) Each specific licensee shall notify the department of health, (~~(division of)~~) radiation protection, in writing, within five working days following the filing of a voluntary or involuntary petition for bankruptcy by or against:

(a) The licensee;

(b) A person controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate of the licensee.

(6) (~~(This)~~) The specific licensee's bankruptcy notification must include:

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

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

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

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

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

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

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

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

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

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

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

(9) Each general licensee that is required to register by WAC 246-233-020 (3)(k) shall notify the department of health, radiation protection, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by or against:

(a) The licensee;

(b) A person controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate of the licensee.

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

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

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

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

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

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

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

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

AMENDATORY SECTION (Amending WSR 00-07-085, filed 3/15/00, effective 4/15/00)

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

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

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

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

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

(a) Terminate use of radioactive material;

(b) Properly dispose of radioactive material;

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

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

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

(ii) If detectable levels of radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the licensee meets the criteria established in chapter 246-246 WAC and the department

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

(4) Each specific licensee who possesses residual radioactive material under subsection (3)(d)(ii) of this section, following the expiration of the facility and/or equipment date specified in the license, shall:

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

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

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

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

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

(5) Each general licensee licensed under the provisions of WAC ((246-233-020(8))) 246-233-040, shall immediately notify the department in writing when the licensee decides to discontinue all activities involving radioactive materials authorized under the general license. Such notification shall include a description of how the generally licensed material was disposed and the results of facility surveys, if applicable, to confirm the absence of radioactive materials.

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

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

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

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

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

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

(8) Coincident with the notification required by subsection (6) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to WAC 246-235-075 or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to subsection (10)(d)(v) of this section. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the

department.

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

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

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

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

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

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

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

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

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

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

(ii) A description of planned decommissioning activities;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per one hundred square centimeters--removable and fixed--for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

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

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

(a) Radioactive material has been properly disposed;

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

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

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

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

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

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

- (a) Records of disposal required by WAC 246-221-230 (8)(a); and
- (b) Records of results required by WAC 246-221-230 (7)(h).

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

- (a) Records of disposal required by WAC 246-221-230 (8)(a); and
- (b) Records of results required by WAC 246-221-230 (7)(h).

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

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

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

NEW SECTION

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

NEW SECTION

WAC 246-233-015 **Certain devices and equipment.** A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, chapters 246-232, 246-221** and 246-222 WAC.

(1) *Static elimination device.* Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device.

(2) *Ion generating tube.* Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device or a total of not more than 50 millicuries of Hydrogen-3 (tritium) per device.

** Attention is directed particularly to the provisions of chapter 246-221 WAC which relate to the labeling of containers.

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

WAC 246-233-020 General (~~licenses*~~ ~~Radioactive material other than source material~~) license--Certain measuring, gauging or controlling devices.

((~~Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.~~))

~~(1) (~~Certain devices and equipment.~~ A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the United States Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, chapters 246-222, 246-221** and 246-222 WAC.~~

~~(a) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device.~~

~~(b) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device or a total of not more than 50 millicuries of Hydrogen-3 (tritium) per device.~~

~~** Attention is directed particularly to the provisions of chapter 246-221 WAC of these regulations which relate to the labeling of containers.~~

~~(2) Reserved.~~

~~(3) Reserved.~~

~~(4) Certain measuring, gauging or controlling devices.~~

~~(a)) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of ~~((b), (c), and (d)) subsections (2), (3), and (4)~~ of this ~~((subsection))~~ section, radioactive material excluding special nuclear material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.~~

~~((b)) (2) The general license in ~~((a))~~ subsection (1) of this ~~((subsection))~~ section applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to WAC 246-235-093 or in accordance with the Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution or transfer of devices to persons generally licensed by the United States Nuclear Regulatory Commission, an agreement state or licensing state**. The devices shall have been received from one of the specific licensees described in this subsection or through a transfer made under subsection (3)(h) of this section.~~

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

~~((c)) (3) Any person who owns, acquires, receives, possesses, uses or~~

transfers radioactive material in a device pursuant to the general license in ~~((a))~~ subsection (1) of this ~~(subsection)~~ section:

~~((i))~~ (a) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

~~((i))~~ (b) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however:

~~((A))~~ (i) Devices containing only krypton need not be tested for leakage of radioactive material; and

~~((B))~~ (ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material need not be tested for any purpose. Devices held in storage in the original shipping container prior to initial installation need not be tested until immediately prior to use;

~~((iii))~~ (c) Shall assure that the tests required by ~~((e)(i))~~ (b) of this subsection and other testing, installing, servicing, and removing from installation involving the radioactive materials, its shielding or containment, are performed:

~~((A))~~ (i) In accordance with the instructions provided by the labels; or

~~((B))~~ (ii) By a person holding a specific license from the department or from the United States Nuclear Regulatory Commission or from any agreement state or from a licensing state to perform such activities;

~~((iv))~~ (d) Shall maintain records showing compliance with the requirements of ~~((e)(i) and (iii))~~ (b) and (c) of this subsection. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removing from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by ~~((e)(i))~~ (b) of this subsection shall be maintained for ~~((one-year))~~ three years after the next required leak test is performed or the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by ~~((e)(i))~~ (b) of this subsection shall be maintained for ~~((one-year))~~ three years after the next required test of the on/off mechanism and indicator is performed or the sealed source is transferred or disposed. Records of other testing, installation, servicing, and removal from installation required by (c)~~((iii))~~ of this subsection shall be maintained for a period of ~~((two))~~ three years from the date of the recorded event or until the device is transferred or disposed;

~~((v))~~ (e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcuries or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the department, the United States Nuclear Regulatory Commission, or from an agreement state or a licensing state to repair such devices, or disposed by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within thirty days, furnish to the department a written report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcuries or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use (see WAC 246-246-020);

~~((+vi))~~ (f) Shall not abandon the device containing radioactive material;

~~((+vii))~~ (g) Except as provided in ~~((+e)-(viii))~~ (h) of this subsection, shall transfer or dispose the device containing radioactive material only by transfer to a person holding a specific license of the department, the United States Nuclear Regulatory Commission, or an agreement state, or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; ~~(and)~~ the name ~~(and)~~, address, and license number of the person receiving the device, and the date of transfer. ~~((No report is required if the device is transferred to the specific licensee in order to obtain a replacement device))~~ Prior written approval from the department is required before transferring the device to any other specific licensee not specifically identified in this subsection;

~~((+viii))~~ (h) Shall transfer the device to another general licensee only:

~~((+A))~~ (i) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this ~~((subsection))~~ section, a copy of WAC 246-221-240, 246-221-250, 246-232-050, and 246-232-060, and any safety documents identified in the label of the device and within thirty days of the transfer, report to the department the manufacturer's (or transferor's) name, model number, and serial number of device transferred, the transferee's name and mailing address (of the transferee) for the location of use, and the name (and/or position of an individual who may constitute a point of contact between the department and the transferee), title, and phone number of the responsible individual identified by the transferee in accordance with (j) of this subsection to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

~~((+B))~~ (ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee~~((+))~~;

~~((+C))~~ (i) Shall comply with the provisions of WAC 246-221-240 and 246-221-250 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of chapters 246-221 and 246-222 WAC;

(j) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(k)(i) Shall register, in accordance with (k)(i) and (iii) of this subsection, devices containing at least 370 MBq (10 mCi) of Cesium-137, 3.7 MBq (0.1 mCi) of Strontium-90, 37 MBq (1 mCi) of Cobalt-60, or 37 MBq (1 mCi) of Americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under (k)(iii)(D) of this subsection, represents a separate general licensee and requires a separate registration and fee;

(ii) If in possession of a device meeting the criteria of (k)(i) of this subsection, shall register these devices annually with the department and shall pay the fee required by WAC 246-254-090. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the department. The registration information must be submitted to the department within thirty days of the

date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of (k)(i) of this subsection is subject to the bankruptcy notification requirement in WAC 246-232-050;

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the department:

(A) Name and mailing address of the general licensee;

(B) Information about each device: The manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label);

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under (j) of this subsection;

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license;

(iv) Persons generally licensed by the U.S. Nuclear Regulatory Commission, or an agreement state with respect to devices meeting the criteria in (k)(i) of this subsection are not subject to registration requirements if the devices are used in areas subject to Washington state jurisdiction for a period less than one hundred eighty days in any calendar year. The department will not request registration information from such licensees;

(l) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the department within thirty days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

(m) Shall not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by (b) of this subsection need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

~~((d))~~ (4) The general license in ~~((a))~~ subsection (1) of this ~~((subsection))~~ section does not authorize the manufacture, import or export of devices containing radioactive material.

~~((e))~~ (5) The general license provided in this subsection is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-221-240, 246-221-250, 246-232-050, 246-232-060, 246-232-070, 246-232-080, and 246-232-090.

~~((5) Luminous safety devices for aircraft.~~

~~(a) A general license is hereby issued to own, receive, acquire, possess and use tritium or Promethium 147 contained in luminous safety devices for use in aircraft, provided:~~

~~(i) Each device contains not more than 10 curies of tritium or 300 millicuries of Promethium 147, and~~

~~(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission, or each device has been manufactured or assembled in~~

~~accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.~~

~~(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this subsection are exempt from the requirements of chapters 246-221 and 246-222 WAC except that they shall comply with the provisions of WAC 246-221-240 and 246-221-250.~~

~~(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or Promethium-147.~~

~~(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of Promethium 147 contained in instrument dials.~~

~~(e) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.~~

~~(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.~~

~~(7) Calibration and reference sources.~~

~~(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of (d) and (e) of this subsection, Americium 241 in the form of calibration or reference sources.~~

~~(i) Any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material, or~~

~~(ii) Any person who holds a specific license issued by the United States Nuclear Regulatory Commission which authorizes that person to receive, possess, use and transfer special nuclear material.~~

~~(b) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of (d) and (e) of this subsection to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.~~

~~(c) A general license is hereby issued to own, receive, possess, use and transfer Radium 226 in the form of calibration or reference sources in accordance with the provisions of (d) and (e) of this subsection to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.~~

~~(d) The general licenses in (a), (b) and (c) of this subsection apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department or any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the United States Nuclear Regulatory Commission.~~

~~(e) The general licenses provided in (a), (b) and (c) of this subsection are subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, 246-232-090, chapters 246-221 and 246-222 WAC.~~

~~In addition, persons who own, receive, acquire, possess, use or~~

~~transfer one or more calibration or reference sources pursuant to these general licenses:~~

~~(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of Americium 241 and 5 microcuries of plutonium and 5 microcuries of Radium 226 in such sources,~~

~~(ii) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:~~

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

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

~~Name of manufacturer or importer~~

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

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

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

~~Name of manufacturer or importer~~

~~(iii) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the United States Nuclear Regulatory Commission, or an agreement state or licensing state to receive the source,~~

~~(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain Americium-241, Plutonium, or Radium-226/Radon-222 which might otherwise escape during storage, and~~

~~(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.~~

~~(f) These general licenses do not authorize the manufacture of calibration or reference sources containing Americium-241, Plutonium, or Radium-226.~~

~~(g) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*~~

~~(a) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of or use, for any of the following stated tests, in accordance with the provisions of (b), (c), (d), (e), and (f) of this subsection the following radioactive materials in prepackaged units:~~

~~(i) Iodine 125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(ii) Iodine 121, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(iii) Carbon 14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(iv) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(v) Iron 59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(vi) Cobalt 57, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(vii) Selenium 75, in units not to exceed 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

~~(viii) Mock Iodine 125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine 129 and 0.005 microcurie of Americium 241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.~~

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

~~(b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by (a) of~~

~~this subsection until that person has received a validated copy of department Form RHF 15 "Certificate in vitro testing with radioactive material under general license." Annual validation requires resubmittal of revised department Form RHF 15 and submittal of the annual fee to the department. The physician, veterinarian, clinical laboratory or hospital shall furnish on department Form RHF 15 the following information and such other information as may be required by that form.~~

~~(i) Name and address of the physician, veterinarian, clinical laboratory or hospital;~~

~~(ii) The location of use; and~~

~~(iii) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in (a) of this subsection and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.~~

~~(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by (a) of this subsection shall comply with the following:~~

~~(i) The general licensee shall not possess at any one time, pursuant to the general license in (a) of this subsection at any one location of storage or use, a total amount of Iodine 125, Iodine 131, Selenium 75, Iron 59, and/or Cobalt 57 in excess of 200 microcuries.~~

~~(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.~~

~~(iii) The general licensee shall use the radioactive material only for the uses authorized by (a) of this subsection.~~

~~(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.~~

~~(v) The general licensee shall dispose of the Mock Iodine 125 reference or calibration sources described in (a)(viii) of this subsection as required by WAC 246-221-170.~~

~~(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to (a) of this subsection:~~

~~(i) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to WAC 246-235-097 or in accordance with the provisions of a specific license issued by the United States Nuclear Regulatory Commission, or any agreement state or licensing state which authorizes the manufacture and distribution of Iodine 125, Iodine 131, Carbon 14, Hydrogen 3 (tritium), Iron 59, Selenium 75, Cobalt 57, or Mock Iodine 125 to persons generally licensed under this subsection or its equivalent; and~~

~~(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:~~

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

~~subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.~~

Name of manufacturer

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

Name of manufacturer

~~(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of (a) of this subsection shall report in writing to the department, any changes in the information previously furnished in the "Certificate in vitro testing with radioactive material under general license," department Form RHF-15. The report shall be furnished within thirty days after the effective date of such change.~~

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

~~(g) Ice detection devices.~~

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

~~(b) Persons who own, receive, acquire, possess, use or transfer Strontium-90 contained in ice detection devices pursuant to the general license in (a) of this subsection:~~

~~(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States Nuclear Regulatory Commission or an agreement state to manufacture or service such devices, or shall dispose of the device pursuant to the provisions of these regulations;~~

~~(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and~~

~~(iii) Are exempt from the requirements of chapters 246-221 and 246-222 WAC except that such persons shall comply with the provisions of WAC 246-221-170, 246-221-240, and 246-221-250.~~

~~(c) This general license does not authorize the manufacture, assembly, disassembly or repair of Strontium-90 sources in ice detection devices.~~

~~(d) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.)~~

NEW SECTION

WAC 246-233-025 General license--Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess and use tritium or Promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) Each device contains not more than 10 curies of tritium or 300 millicuries of Promethium-147; and

(b) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the United States Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the department or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the United States Nuclear Regulatory Commission.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this subsection are exempt from the requirements of chapters 246-221 and 246-222 WAC except that they shall comply with the provisions of WAC 246-221-240 and 246-221-250.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or Promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of Promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-050, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.

NEW SECTION

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

(2) Persons who own, receive, acquire, possess, use or transfer Strontium-90 contained in ice detection devices pursuant to the general license in (a) of this subsection:

(a) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the United States Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of these regulations;

(b) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(c) Are exempt from the requirements of chapters 246-221 and 246-222 WAC except that such persons shall comply with the provisions of WAC 246-221-170, 246-221-240, and 246-221-250.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of Strontium-90 sources in ice detection devices.

(4) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, and 246-232-090.

NEW SECTION

WAC 246-233-035 General license--Calibration and reference sources.

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

(a) Any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material; or

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

(2) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections (4) and (5) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use and transfer Radium-226 in the form of calibration or reference sources in accordance with the provisions of subsections (4) and (5) of this section to any person who holds a specific license issued by the department which authorizes that person to receive, possess, use and transfer radioactive material.

(4) The general licenses in subsections (1), (2) and (3) of this section apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the United States Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the department or any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the United States Nuclear Regulatory Commission.

(5) The general licenses provided in subsections (1), (2) and (3) of this section are subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-232-050, 246-232-070, 246-232-080, 246-232-090, chapters 246-221 and 246-222 WAC.

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

(a) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of Americium-241 and 5 microcuries of plutonium and 5 microcuries of Radium-226 in such sources;

(b) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

(i)

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

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

Name of manufacturer or importer

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

(ii)

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

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

Name of manufacturer or importer

(c) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the department, the United States Nuclear Regulatory Commission, or an agreement state or licensing state to receive the source;

(d) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain Americium-241, plutonium, or Radium-226/Radon-222 which might otherwise escape during storage; and

(e) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing Americium-241, plutonium, or Radium-226.

NEW SECTION

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

(a) Iodine-125, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(b) Iodine-131, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(c) Carbon-14, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(d) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(e) Iron-59, in units not exceeding 20 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(f) Cobalt-57, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(g) Selenium-75, in units not to exceed 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(h) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal

Deleted: in accordance with the provisions of or use, for any of the following stated tests.

or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

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

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (1) of this section until that person has received a validated copy of department Form RHF-15 "Certificate - in vitro testing with radioactive material under general license." Annual validation requires resubmittal of revised department Form RHF-15 and submittal of the annual fee to the department. The physician, veterinarian, clinical laboratory or hospital shall furnish on department Form RHF-15 the following information and such other information as may be required by that form:

(a) Name and address of the physician, veterinarian, clinical laboratory or hospital;

(b) The location of use; and

(c) A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in subsection (1) of this section and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subsection (1) of this section shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in subsection (1) of this section at any one location of storage or use, a total amount of Iodine-125, Iodine-131, Selenium-75, Iron-59, and/or Cobalt-57 in excess of 200 microcuries.

(b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(c) The general licensee shall use the radioactive material only for the uses authorized by subsection (1) of this section.

(d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subsection (1)(h) of this section as required by WAC 246-221-170.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subsection (1) of this section:

(a) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to WAC 246-235-097 or in accordance with the provisions of a specific license issued by the United States Nuclear Regulatory Commission, or any agreement state or licensing state which authorizes the manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (tritium), Iron-59, Selenium-75, Cobalt-57, or Mock Iodine-125 to persons generally licensed under this subsection or its equivalent; and

(b) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

Name of manufacturer

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

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (1) of this section shall report in writing to the department, any changes in the information previously furnished in the "Certificate - in vitro testing with radioactive material under general license," department Form RHF-15. The report shall be furnished within thirty days after the effective date of such change.

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

AMENDATORY SECTION (Amending WSR 98-13-037, 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(~~((4))~~) or equivalent regulations of the United States Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

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

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

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

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

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

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

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

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

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

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

(A) The receipt, possession, use and transfer of this device, Model, Serial No. Note*, are subject to a general license or the equivalent, and the regulations of the United States Nuclear Regulatory Commission or a state with which the United States Nuclear

Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

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

CAUTION - RADIOACTIVE MATERIAL

(Name of manufacturer or distributor)*

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

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

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

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a 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((+4)), or under equivalent regulations of the United States

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

(4) Each person licensed under subsection (1) of this section to distribute or initially transfer devices to generally licensed persons shall, prior to the transfer to the intended user or the initial transfer to an intermediate person, if used:

(a) Furnish to the intended user and to each person to whom a device is transferred as an intermediary, the following:

(i) A copy of the general license contained in WAC 246-233-020 (~~(+4)~~) to each person to whom the person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in WAC 246-233-020(~~4~~)). 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;

(b) Furnish to the intended user in another jurisdiction and to each person to whom a device is transferred as an intermediary, the following:

(i) A copy of the ((general license)) appropriate regulations, equivalent to WAC 246-233-020, 246-232-050, 246-221-230, 246-221-240, and 246-221-250, contained in the United States Nuclear Regulatory Commission's, agreement state's, or licensing state's regulation ((equivalent to WAC 246-233-020(~~4~~)), or alternatively, furnish a copy of the general license contained in WAC 246-233-020(~~4~~) to each person to whom, directly or through an intermediate person, is transferred radioactive material in a device for use pursuant to the general license of the United States Nuclear Regulatory Commission, the agreement state or the licensing state)). If a copy of the general license in WAC 246-233-020(~~(+4)~~) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the United States Nuclear Regulatory Commission, agreement state or licensing state under requirements substantially the same as those in WAC 246-233-020(~~(+4)~~)). 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 regulatory agency from which additional information may be obtained; and

(v) An indication that U.S. Nuclear Regulatory Commission policy is to issue high civil penalties for improper disposal;

(c) Report to the department all transfers of such devices to persons for use under the general license in WAC 246-233-020(~~(+4)~~) and all receipts of devices from persons licensed under WAC 246-233-020.

(i) Such report shall ((identify)) include:

(A) The identity of each general licensee by name and mailing address ((, an individual by name and/or position who may constitute a point of contact between the department and the general licensee,)) for the location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

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

(C) The date of transfer;

(D) The type ((and)), model number and serial number of device transferred((~~7~~)); and

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

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(iii) For devices received from persons generally licensed 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;

(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((~~4~~)) during the reporting period, the report shall so indicate.

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

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

(d) Reports to other departments.

(i) Report to the United States Nuclear Regulatory Commission all transfers of such devices to persons for use under the United States Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31 and all receipts of devices therefrom.

(ii) Report to the responsible department all transfers of devices manufactured and distributed pursuant to this section for use under a general license in that state's regulations equivalent to WAC 246-233-020((~~4~~)) and all receipts of devices from persons generally licensed under WAC 246-233-020 or equivalent.

(iii) Such reports shall ((identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the department and the general licensee,)) include:

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

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

actions to ensure compliance with the appropriate regulations and requirements;

(C) The date of transfer;

(D) The type and model of the device transferred(~~(7)~~); and

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

(iv) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(v) For devices received from persons generally licensed 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;

(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 WAC 246-233-020, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(vii) The report shall be submitted within thirty days after the end of each calendar quarter in which such a device is transferred to the generally licensed person and shall clearly indicate the period covered by the report.

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

(ix) If no transfers have been made to United States Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the United States Nuclear Regulatory Commission.

~~((iv))~~ (x) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible department upon request of the department.

~~(e) Keep records ((showing the name, address and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in WAC 246-233-020(4), or equivalent regulations of the United States Nuclear Regulatory Commission, an agreement state or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of subsection (4) of this section)) concerning transfers and receipts of devices that support the reports required by this section. Records required by this section shall be maintained for a period of three years following the date of the recorded event.~~

(f) If a notification of bankruptcy has been made under WAC 246-233-050 or the license is to be terminated, each person licensed under this section shall provide, upon request, to the department, the United States Nuclear Regulatory Commission, an agreement state, or a licensing state, records of final disposition required under subsection (4) of this section.

AMENDATORY SECTION (Amending WSR 98-13-037, 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 or repair luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under WAC ((~~246-233-020(5)~~)) 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, 32.56, 32.101 of 10 CFR Part 32 or their equivalent.

(2) *Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under WAC ((~~246-233-020(7)~~))* 246-233-035. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under WAC ((~~246-233-020(7)~~)) 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, 32.59, 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR 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 ((~~246-233-020(9)~~)) 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, 32.62, 32.103 of 10 CFR Part 32 are met.

AMENDATORY SECTION (Amending WSR 98-13-037, 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 ((~~246-233-020(8)~~)) 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 10 microcuries each;

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

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

- (d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
- (e) Iron-59 in units not exceeding 20 microcuries each;
- (f) Cobalt-57 in units not exceeding 10 microcuries each;
- (g) Selenium-75 in units not exceeding 10 microcuries each;
- (h) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 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 10 microcuries of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 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 United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

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

Name of manufacturer

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

AMENDATORY SECTION (Amending WSR 94-06-017, filed 2/22/94, effective 3/25/94)

WAC 246-239-080 Calibration and reference sources. (1) Any licensee who owns, receives, acquires, possesses, uses, or transfers calibration reference sources pursuant to the general license authorized in WAC ((246-233-020(7-)) 246-233-035 shall:

(a) Maintain a file or log identifying such sources, including nuclide, activity, model and serial numbers, manufacturer, date of receipt, date of transfer, and to whom transferred (where applicable);

(b) Possess at any one time, and at any one location of storage or use, no more than five uCi (0.185 megabecquerels) of Am-241 and five uCi (0.185 megabecquerels) of Pu and five uCi (0.185 megabecquerels) of Ra-226 in such sources;

(c) Store such source(s), except when the source(s) is being used, in a closed container adequately designed and constructed to contain Americium-241, Plutonium, or Radium 226 which might otherwise escape during storage; and

(d) Not use such source(s) for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(2) Any licensee who receives, possesses, or uses calibration and reference standards pursuant to the group licensing provisions of WAC 246-235-080 (3)(c):

(a) Shall conduct leak tests in accordance with WAC 246-235-080 (3)(d);

(b) Shall follow the radiation safety and handling instructions approved by the department, the United States Nuclear Regulatory Commission, and agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(c) Shall conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventory shall be maintained for inspection by the department, and shall include, but not be limited to, the quantities and kinds of radioactive material, the serial number of each source, location of sources, the initials or name of the person performing the inventory, and the date of inventory.

(3) Any licensee authorized for medical Group I, II, or III is also authorized to receive, use, possess, store, transfer and/or dispose of sealed sources containing Cobalt-57 in amounts not exceeding 22 millicuries (814 megabecquerels) per source which are designed, intended, and used solely for required imaging system or dose calibrator quality assurance tests.