For Part 30.15

333-102-0015 (see (1)(f) and (g)

Certain Items Containing Radioactive Material

(1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these rules to the extent that he or she receives, possesses, uses, transfers, owns or acquires the following products:

NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(A) 25 millicuries (925 MBq) of tritium per timepiece;

(B) Five millicuries (185 MBq) of tritium per hand;

(C) 15 millicuries (555 MBq) of tritium per dial (when used, bezels must be considered as part of the dial);

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

(E) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;

(F) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (when used, bezels must be considered as part of the dial);

(G) 0.15 microcurie (5.55 kBq) of radium per timepiece;

(H) 0.03 microcurie (1.11 kBq) of radium per hand;

(I) 0.09 microcurie (3.33 kBq) of radium per dial (when used, bezels must be considered as part of the dial);

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

(i) For wrist watches, 0.1 millirad (one Gy) per hour at 10 centimeters from any surface;

(ii) For pocket watches, 0.1 millirad (one Gy) per hour at one centimeter from any surface; and

(iii) For any other timepiece, 0.2 millirad (two Gy) per hour at 10 centimeters from any surface.

(K) One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;

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

(d) Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;

(B) One microcurie (37 kBq) of cobalt-60;

(C) Five microcuries (185 kBq) of nickel-63;

(D) 30 microcuries (1.11 MBq) of krypton-85;

(E) Five microcuries (185 kBq) of cesium-137; or

(F) 30 microcuries (1.11 MBq) of promethium-147.

(G) And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

NOTE: For purposes of, subsection (1)(d) of this rule "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

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

(A) Each source contains no more than one exempt quantity set forth in 10 CFR Part 30.71 Schedule B; and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR Part 30.71 Schedule B provided that the sum of such fractions must not exceed unity.

(C) For americium-241, 0.05 microcuries (1.85 kBq) is considered an exempt quantity under paragraph (1)(e)(A) of this rule. Ionization chamber smoke detectors containing not more than one microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(f) Static elimination devices that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium 210 per device.

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

(h) Such devices authorized before October 23, 2012 for use under the general license then provided in 10 CFR Part 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission.

(2) The exemptions contained in this rule must not authorize any of the following:

(a) The manufacture of any product listed;

(b) The application or removal of radioactive luminous material to or from meters and timepieces or hands and dials therefore;

(c) The installation into automobile locks of illuminators containing tritium or promethium-147 or the application of tritium to balances of precision or parts thereof;

(d) Human use, or the use in any device or article, except timepieces, which is intended to be placed on or in the human body;

(e) As applied to radioactive material exempted under section (1) of this rule, the production, packaging, repackaging or transfer of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

For Part 30.19

333-102-0030

Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in section (3) of this rule, any person is exempt from the requirements for a license set forth in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to OAR 333-102-0245, which authorizes the initial transfer of the product for use under this section.

(2) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under section (1) of this rule, shall apply for a license under OAR 333-102-0245 and for a certificate of registration in accordance with 10 CFR Part 32.210.

(3) The exemption in section (1) of this rule does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

For Part 30.20

333-102-0025

Gas and Aerosol Detectors Containing Radioactive Material

(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license and from the rules in this division and in divisions 105, 113, 115, 116, 117, 120, and 121 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Parts 32.26 of; or a Licensing State pursuant to OAR 333-102-0260, which authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a state under comparable provisions to OAR 333-102-0260 authorizing distribution to persons who are exempt from regulatory requirements.

(2) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct materials, or to initially transfer such products for use under section (1) of this rule shall apply for a license under OAR 333-102-0260 and for a certificate of registration in accordance with 10 CFR Part 32.210.

(3) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State must be considered exempt under section (1) of this rule, provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of OAR 333-102-0260.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 20-2010, f. & cert. ef. 9-1-10; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Part 30.22

333-102-0033

Certain Industrial Devices

(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material 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 an ionized atmosphere, any person is exempt from the requirements for a license set forth in rules in this division and in divisions 105, 113, 115, 116, 117, 120, and 121 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under this division, which authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(2) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under section (1) of this rule shall apply for a license under this division and for a certificate of registration in accordance with 10 CFR Part 32.210.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 – 453.807
Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

For Part 30.32

333-102-0190

Application for Specific Licenses

(1) Applications for specific licenses must be filed on a form prescribed by the Authority. Information contained in previous applications, statements or reports filed with the Authority, the US Nuclear Regulatory Commission, or an Agreement State or a Licensing State or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(2) The Authority may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Authority to determine

whether the application shall be granted or denied or whether a license shall be modified or revoked.

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

(4) Each applicant for a specific license is required to have a permanent in-state office with a copy of all required records available for inspection by the Authority.

(5) An application for a license filed pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with rules of the Authority and the US Nuclear Regulatory Commission as to applications for such licenses.

(6) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in OAR 333-103-0010.

(7) An application for a license to receive and possess radioactive material for the conduct of any activity that the Authority has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect the quality of the environment, must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.

(8) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR Parts 32.210; or

(b) Contain the information identified in 10 CFR Part 32.210(c); or

(c) For sources or devices manufactured prior to October 23, 2012 that are not registered with the Nuclear Regulatory Commission or an Agreement State which the applicant is unable to provide all categories of information specified in 10 CFR Part 32.210(c) the applicant must provide:

(A) All available information identified in 10 CFR Part 32.210(c) concerning the source and if applicable the device; and

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

(i) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR Part 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

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

(9) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:

(10)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

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

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

(b) One or more of the following factors may be used to support an evaluation submitted under paragraph (10)(a)(A) of this rule:

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

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

(C) The release fraction in the respirable size range shall be lower than the release fraction shown in 10 CFR Part 30.72 (Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) due to the chemical or physical form of the material;

(D) The solubility of the radioactive material shall reduce the dose received;

(E) Facility design or engineered safety features in the facility shall cause the release fraction to be lower than shown in 10 CFR Part 30.72;

(F) Operating restrictions or procedures shall prevent a release fraction as large as that shown in 10 CFR Part 30.72; or

(G) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under paragraph (10)(a)(B) of this rule must include the following information:

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

(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.

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

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

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

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

(G) Responsibilities. A brief description of the responsibilities of licensee personnel if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations and the Authority; also responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee also must commit to notify the Authority immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not supercede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Authority.

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

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

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

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

(N) An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or division 116 of this chapter or equivalent Agreement State requirements shall include:

(i) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(ii) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2).

(iii) Identification of individual(s) authorized to prepare the PET radiopharmaceutical drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in OAR 333-116-0880 and 333-116-0910.

(iv) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.

(v) Each applicant for a license for byproduct material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in 10 CFR Parts 73.21, 73.22 and 73.23 as applicable.

(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Authority. The licensee must provide any comments received within the 60 days to the Authority with the emergency plan.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

For Part 31.3

OAR 333-102-0105 is removed

Certain devices and equipment

For Part 32.51

333-102-0235

Requirements for License to Manufacture, or Initially Transfer Radioactive Material Contained in Devices Granted a General License Under OAR 333-102-0115

(1) An application for a specific license to manufacture, or initially transfer devices containing radioactive material, excluding special nuclear material, to persons granted a general license by

OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(a) The applicant satisfies the general requirements of OAR 333-102-0200;

(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:

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

(B) 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 annual limits specified in OAR 333-120-0100; and

(C) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person may receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR Part 32.24:

(i) Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye 150 mSv (15 rem);

(ii) Hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter two Sv (200 rem);

(iii) Other organs 500 mSv (50 rem).

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

(A) 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);

(B) The requirements, or lack of requirement, for leak testing, or for testing of 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

(C) The information called for in the following statement in the same or substantially similar form:

The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label must be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION — RADIOACTIVE MATERIAL

_____

(Name of manufacturer or initial transferor)

(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 OAR 333-120-0400, and the name of the manufacturer or initial distributor.

(E) Each device meeting the criteria of OAR 333-102-0115(9)(a), bears a permanent label, such as being embossed, etched, stamped, or engraved, 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 OAR 333-120-0400.

(F) The device has been registered in the Sealed Source and Device Registry

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or both, the applicant must include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that 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 Authority will consider information that includes, but is not limited to:

(a) Primary containment (source capsule);

(b) Protection of primary containment;

(c) Method of sealing containment;

(d) Containment construction materials;

(e) Form of contained radioactive material;

(f) Maximum temperature withstood during prototype tests;

(g) Maximum pressure withstood during prototype tests;

(h) Maximum quantity of contained radioactive material;

(i) Radiotoxicity of contained radioactive material; and

(j) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under OAR 333-102-0115, or under equivalent rules of the U.S. 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 must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this 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 a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100.

(4) Prior to transfer of a device to a person granted a general license by OAR 333-102-0115(1), the licensee must:

(a) Furnish a copy of the general license contained in OAR 333-102-0115 to each person to whom the licensee directly, or through an intermediate person, transfers radioactive material in a device for use pursuant to the general license contained in 333-102-0115;

(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State's rules equivalent to OAR 333-102-0115. Alternatively, a copy of the general license contained in 333-102-0115 must be furnished to each person to whom directly, or through an intermediate person, is transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State under requirements substantially the same as those in 333-102-0115;

(c) Report to the Authority all transfers of such devices to persons for use under the general license in OAR 333-102-0115. Such report must identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. 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 must include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons granted a

general license by 333-102-0115 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days after the end of each quarter;

(d) Furnish reports to other agencies:

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 31.5 of 10 CFR Part 31. Reports must be submitted on the NRC form "Transfers of Industrial Devices Report" or on a clear and legible report containing all of the data required by the form. The required information includes:

(i) The identity of each general licensee by name and address;

(ii) The name and phone number of the person designated by the general licensee to be responsible for ensuring compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

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

(v) The quantity and type of byproduct material contained in the device.

(B) 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 must include the same information for each intermediate person, and clearly designate that person as an intermediate person.

(C) If the device transferred replaced another returned by the general licensee, report also the type, model number, and serial number of the one returned.

(D) If no transfers have been made to persons generally licensed under 10 CFR 31.5 or OAR 333-102-0115 during the reporting period, the report must so indicate.

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

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

(e) Report to the responsible Agreement or Licensing State Authority all transfers of such devices to persons for use under a general license in an Agreement State's regulations equivalent to OAR 333-102-0115. Such reports must identify all of the information in 333-102-0235(4)(d) of this rule, including each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Authority and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material

contained in the device. 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 must include identification of each intermediate person by name, address, contact and relationship to the intended user. The report must be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person granted a general license;

(f) If no transfers have been made to U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission;

(g) If no transfers have been made to persons granted a general license within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Authority;

(h) Keep records showing the name, address and the point of contact for each general licensee to whom directly, or through an intermediate person is transferred radioactive material in devices for use pursuant to the general license provided in OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records must show the date of each transfer, the isotope and the quantity of radioactive material in each device transferred, the identity of any intermediate person and compliance with the reporting requirements of subsection (4)(h) of this rule. Records required by this rule must be maintained for a period of three years following the estimated useful life of the device or the date of final disposition, if known;

(i) Furnish a list of the services that only can be performed by a specific licensee, and information on acceptable disposal options, including estimated costs of disposal, to each person to whom he directly, or through an intermediate person, transfers radioactive material in a device for use under the general license granted in OAR 333-102-0115;

(j) Furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. If a copy of the general license in OAR 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State.

(k) Label each device transferred if more than one year after the effective date of this rule in accordance with the labeling requirements in 10 CFR Part 32.51(a)(3) through (5).

(l) If a notification of bankruptcy has been made under 10 CFR Part 30.34(h) or the license is to be terminated, provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under 10 CFR Part 32.52(c).

(5) License Conditions.

(a) If a device containing radioactive material is to be transferred for use under the general license contained in OAR 333-102-0115, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be

transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the general license contained in OAR 333-102-0115; if 333-102-0115(4)(b) through (d) or 333-102-0115(8) do not apply to the particular device, those sections may be omitted;

(B) A copy of OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710;

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

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

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of the Agreement State's regulations equivalent to OAR 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710 or a copy of 10 CFR Secs. 31.5, 31.2, 30.51, 20.2201, and 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State. If certain sections of the regulations do not apply to the particular device, those sections may be omitted;

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

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

(D) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or the Nuclear Regulatory Commission from which additional information may be obtained.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp),

f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

For Parts 32.53, 32.55, 32.56

333-102-0265

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 granted a general license by OAR 333-102-0110 will be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200; and

(2) The applicant satisfies the requirements of sections 32.53, 32.54, 32.55, 32.56, 32.101, and 32.110 of 10 CFR Part 32 or their equivalent.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 32.57 and 32.59

333-102-0270

Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Granted a General License by OAR 333-102-0125

An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons granted a general license by OAR 333-102-0125 will be approved if:

(1) The applicant satisfies the general requirement of OAR 333-102-0200; and

(2) The applicant satisfies the requirements of sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and section 70.39 of 10 CFR Part 70 or their equivalent.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

For Parts 32.61 and 32.62

333-102-0275

Licensing the Manufacture and Distribution of Ice Detection Devices

An application for a specific license to manufacture and distribute ice detection devices to persons granted a general license by OAR 333-102-0135 will be approved if:

(1) The applicant satisfies the general requirements of OAR 333-102-0200;

(2) The criteria of sections 32.61, 32.62, 32.103, and 32.110 of 10 CFR Part 32 are met.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 4-2007, f. & cert. ef. 3-1-07

For Part 32.74

333-102-0290

Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use

(1) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to division 116 of this chapter for use as a calibration, transmission, or reference source, or for the uses listed in OAR 333-116-0400, 333-116-0420, 333-116-0480 and 333-116-0485 will be approved if:

(a) The applicant satisfies the general requirements in OAR 333-102-0200.

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

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

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

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

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

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

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

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

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

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in OAR 333-116-0190, 333-116-0400, or 333-116-0420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(d) The source or device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months:

(a) The applicant must include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(b) In determining the acceptable interval for test of leakage of radioactive material, the Authority will consider information that includes, but is not limited to:

(A) Primary containment or source capsule;

(B) Protection of primary containment;

(C) Method of sealing containment;

(D) Containment construction materials;

(E) Form of contained radioactive material;

(F) Maximum temperature withstood during prototype tests;

(G) Maximum pressure withstood during prototype tests;

(H) Maximum quantity of contained radioactive material;

(I) Radiotoxicity of contained radioactive material; and

(J) Operating experience with identical sources or devices similarly designed and constructed sources or devices.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15