

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

General Licenses -- Radioactive Material Other than Source Material

333-102-0105 repealed for Part 30.15(a)(2) and rule moved to 333-102-0015(1)(f) and (g)

~~333-102-0105~~

~~Certain Devices and Equipment~~

~~A general license is hereby granted to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment that have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), and 333-100-0065 (Tests), 333-102-0010(2) (Exempt Concentrations), 333-102-0305(1) through 333-102-0305(7) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of Material), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, 118, and 120 of this chapter.~~

~~**NOTE:** Attention is directed particularly to the provisions of division 120 of this chapter that relate to the labeling of containers (OAR 333-120-0430 and 333-120-0440).~~

~~(1) Static Elimination Devices. Devices designed for use as static eliminators that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium 210 per device;~~

~~(2) Ion Generating Tubes. Devices designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium 210 per device or a total of not more than 1.85 GBq (50 millicuries) of hydrogen 3 (tritium) per device.~~

~~**NOTE:** Different general licenses are issued in this division, each of which has its own specific conditions and requirements.~~

~~[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 4-2007, f. & cert. ef. 3-1-07; PH 4-2010, f. & cert. ef. 2-16-10

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

333-102-0015 for Part 30.15(a)(2) and Part 30.19(b)

Certain Items Containing ~~Byproduct Material~~ ~~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;

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

(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

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

(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.

(i) 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 which 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 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.

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Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

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

333-102-0025 for Part 30.20

Gas and Aerosol Detectors Containing ~~Radioactive Material~~ Byproduct Material

(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing ~~byproduct radioactive~~ 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 life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been and~~ manufactured, ~~processed, produced, or initially imported or~~ 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.

~~**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.~~

~~(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 should apply for a license under 333-102-0260 of this division and for a certificate of registration in accordance with 10 CFR Part 32.210. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement 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 of the generally licensed device, and provided further that they meet the requirements of OAR 333-102-0260.~~

(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

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

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

333-102-0030 for Part 30.19

Self-Luminous Products Containing ~~Radioactive Material 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 license authorizes the initial transfer of the product for use under this section.~~

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~~(1) Except for persons who manufacture, process, produce or initially transfer for sale or distribution self luminous products containing radioactive 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, 121 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in self luminous products designed to protect life or property from fires and airborne hazards provided that the products containing radioactive material must have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to OAR 333-102-0265, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.~~

~~**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.~~

~~(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, should apply for a license under OAR 333-102-0245 and for a~~

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Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

~~certificate of registration in accordance with 10 CFR Part 32.210. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement 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 of the generally licensed device, and provided further that they meet the requirements of OAR 333-102-0265.~~

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~~(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. 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 333-102-0265.~~

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~~{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

333-102-0033 for Part 30.22

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 division 102 of this chapter, which license 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.~~

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~~(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, should apply for a license under division 102 of this chapter and for a certificate of registration in accordance with 10 CFR Part 32.210.~~

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333-102-0190 for Part 30.32(g)

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

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 should be granted or denied or whether a license should be modified or revoked.

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

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

(c) For ~~s~~Sources or devices ~~containing naturally occurring or accelerator produced radioactive material~~ manufactured prior to ~~November 30, 2007~~ **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.

~~(C) 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.~~

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

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(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:

~~NOTE: If a renewal application was submitted on or before July 27, 1990, the decommissioning information may follow the renewal application but must be submitted prior to the license being issued.~~

OAR 333-102-0105 is removed for 31.3 (see top of page 1 for 333-102-0105)

333-102-0235 for Part 32.51(a)(6)

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;

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

(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 would 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

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4

(Name of manufacturer or initial transferor)

~~NOTE: Devices licensed under 10 CFR Part 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975. The model, serial number, and name of manufacturer, or initial transferor 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 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 (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 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;

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical devices or similarly designed and constructed devices.

**333-102-0265 for Parts 32.53(b),(d),(e),(f); and
32.55; and
32.56**

**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

**333-102-0270 for Part 32.57(d)(2); and (e); and
32.59**

**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.

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

[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

**333-102-0275 for Part 32.61(e)(4), (f), (g); and
Part 32.62(c), (d), and (e)**

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

333-102-0290 for Part 32.74(a)(4)

**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;

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

(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;

**Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70
(77 FR 43666, Published July 25, 2012) RATS ID: 2012-4**

- (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