

DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION

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DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

333-102-0001

Purpose and Scope

(1) This division prescribes rules applicable to all persons in the State of Oregon governing licensing of radioactive material, and for exemptions from licensing requirements. No person may receive, produce, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license pursuant to this division or divisions 105, 113, 115, 116, 117, or 121 of this chapter.

(2) In addition to the requirements of division 102, all licensees are subject to applicable requirements in divisions 100, 103, 111, 118, and 120 of this chapter. The requirements of this division are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this division and a specific requirement in another division of the rules in this chapter, the specific requirement governs.

(3) This division establishes general licenses for the possession and use of source material and depleted uranium, for radioactive material contained in certain items, and for ownership of radioactive material.

(4) This division gives notice to all persons who knowingly provide to any licensee, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's activities subject to this division, that they may be individually subject to ~~Agency~~ **Department** actions pursuant to OAR 333-100-0035 or 333-100-0040.

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(5) This division prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive material for sale or distribution to persons granted a general license by this division or to persons authorized by the US Nuclear Regulatory Commission to distribute to persons exempted from licensing requirements, and it prescribes certain rules governing holders of these licenses. In addition, this division prescribes requirements for the issuance of specific licenses to persons who introduce radioactive material into a product or material owned by or in the possession of the licensee or another and rules governing holders of such licenses. Further, this division describes procedures and prescribes requirements for the issuance

of certificates of registration (governing radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources, which are to be used by persons specifically licensed under this division or equivalent regulations of an Agreement State or the US Nuclear Regulatory Commission.

(6) The ~~Agency~~Department may engage the services of qualified persons in order to assist the ~~Agency~~Department in meeting the requirements of this chapter, including, but not limited to, evaluating information that may be required under OAR 333-102-0200(6).

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(7) Information provided to the ~~Agency~~Department by an applicant for a license or by a licensee or information required by statute or by the ~~Agency~~Department's rules, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

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(8) Each applicant or licensee must notify the ~~Agency~~Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety. An applicant or licensee violates this rule only if the applicant or licensee fails to notify the ~~Agency~~Department of information that the applicant or licensee has identified as having a significant implication for public health and safety. Notification must be provided to the ~~Agency~~Department within two working days of identifying the information. This requirement is not applicable to information that already is required to be provided to the ~~Agency~~Department by other reporting or updating requirements.

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Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.625 - 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; 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

Exemptions

333-102-0005

Source Material

(1) Any person is exempt from this division to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution or alloy.

(2) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person must not refine or process such ore.

(3) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers:

(a) Any quantities of thorium contained in:

(A) Incandescent gas mantles;

(B) Vacuum tubes;

(C) Welding rods;

(D) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;

(E) Germicidal lamps, sun lamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;

(F) Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these; or

(G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(b) Source material contained in the following products:

(A) Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;

(B) Piezoelectric ceramic containing not more than two percent by weight source material;

(C) Glassware containing not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; or

(D) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(c) Photographic film, negatives and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(e) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

(A) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;

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

NOTE: The requirements specified in sections (3)(e)(B) and (3)(e)(C) of this rule need not be met by counterweights manufactured prior to December 31, 1969 provided, that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969, which read CAUTION -- RADIOACTIVE MATERIAL -- URANIUM.

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

(D) This exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(f) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(A) The shipping container is conspicuously and legibly impressed with the legend "CAUTION -- RADIOACTIVE SHIELDING -- URANIUM"; and

(B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(g) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption must not be deemed to authorize either:

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

(B) The receipt, possession, use or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(h) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 185 Bq (0.005 microCi) of uranium; or

(i) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

(4) The exemptions in section (3) of this rule do not authorize the manufacture of any of the products described.

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

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Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; 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

Exemptions -- Radioactive Material Other than Source Material

333-102-0010

Exempt Concentrations

(1) Except as provided in sections (3) or (4) of this rule, any person is exempt from this division to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 10 CFR Part 30.70. ~~Schedule A.~~

(2) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license ~~outlined in OAR 333-102-0005~~ to the extent that he transfers radioactive material contained in a product or material in concentrations not in excess of those specified in 10 CFR Part 30.70 ~~Schedule A~~ and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, or the Nuclear Regulatory Commission, expressly authorizing such introduction. This exemption does not apply to the transfer of ~~byproduct material~~radioactive material

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contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce ~~byproduct material~~~~radioactive material~~ into a product or material knowing or having reason to believe that it will be transferred to persons exempt under section (1) of this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State except in accordance with a specific license issued pursuant to OAR 333-102-0245 or the general license granted by OAR 333-102-0340.

NOTE: 10 CFR Part 30.70 ~~Schedule A~~ is available from the ~~Agency~~Department.

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Health Services, Radiation Protection Services.

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; PH 14-2008, f. & cert. ef. 9-15-08

Exempt Items

333-102-0015

Certain Items Containing ~~Radioactive Material~~Byproduct 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 ten 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 ten centimeters from any surface.

(K) One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to June 1, 1977.

~~(b) Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than two millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed one millirad (10 Gy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;~~

~~(be) 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.;~~

~~(d) Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium;~~

(ce) 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**;

~~(f) Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat;~~

(dg) 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 ten 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 section (1)(dg) 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.

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(eh) 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 ten 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 section (8) of this rule.

~~(i) Spark-gap irradiators containing not more than one microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons per hour (11.4 liters per hour).~~

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

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(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)(2)(e) 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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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

333-102-0020

Resins Containing Scandium-46, Designed for Sand Consolidation in Oil Wells

~~Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins must have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or must have been manufactured in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S.~~

~~Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium 46.~~

~~[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

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 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 radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall 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 333-102-0260, 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) 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 authorizing distribution and provided further that they meet the requirements of OAR 333-102-0260.

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

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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

333-102-0030

Self-Luminous Products Containing Radioactive Material

(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, and 121 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) 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.

(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 333-102-0265.

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

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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

333-102-0035

Exempt Quantities

(1) Except as provided in sections (2), ~~and~~ (3) and (5) of this rule, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in 10 CFR Part 30.71 Schedule B.

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

(3) Any person who possesses radioactive material received or acquired under the general license formerly provided in OAR 333-102-0105(2) is exempt from the requirements for a license set forth in this rule to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 10 CFR Part 30.71 Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.18 of 10 CFR Part 32 or by the ~~Agency~~Department, pursuant to OAR 333-102-0255, which license states that the radioactive material may be transferred by the licensee to persons exempt under this rule or the equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State.

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(5) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in 10 CFR Part 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this rule.

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NOTE: Authority to transfer possession or control by the manufacturer, processor or producer or 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.

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

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Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-2985, 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

333-102-0040

In Vivo Testing in Humans for H. Pylori Using Carbon-14 Labeled Urea

(1) Except as provided in sections (3) and (4) of this rule, any person is exempt from the requirements for a specific license pursuant to this division and divisions 116 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

NOTE: "Nominal variation" as used in this context means + 10% of the reported per capsule dose.

(2) Any person who desires to use the capsules for research involving human subjects must apply for and receive a specific license pursuant to division 102 of this chapter.

(3) Any person who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution such capsules must apply for and receive a specific license pursuant to 10 CFR 32.21.

(4) Nothing in this rule relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

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

333-102-0101

General Licenses -- Source Material

A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive or possess more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(1) Persons who receive, possess, use, or transfer source material pursuant to the general license granted by section (1) of this rule are prohibited from administering source material, or the radiation therefrom, either externally or internally to human beings except as may be authorized by the ~~Agency~~ Department, in a specific license.

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(2) Persons who receive, possess, use or transfer source material pursuant to the general license granted by section (1) of this rule are exempt from the provisions of divisions 111 and 120 of this chapter to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption must not be deemed to apply to any such person who also is in possession of source material under a specific license issued pursuant to this division.

(3) A general license is hereby granted authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(4) Persons who receive, acquire, possess or use source material pursuant to the general license granted by section (1) of this rule must develop and maintain procedures to establish physical control over the source material and prevent transfer of such source material to persons not authorized to receive the source material.

(5) A person who receives, acquires, possesses or uses source material pursuant to the general license granted by section (1) of this rule:

(a) Must not introduce such source material, in any form, into a chemical, physical, or metallurgical treatment or process;

(b) Must not abandon such source material; and

(c) Must transfer or dispose of such source material only by transfer in accordance with the provisions of OAR 333-102-0330 or 333-120-0500.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; 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

Exempt Items

333-102-0103

General Licenses -- Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby granted to receive, acquire, possess, use or transfer, in accordance with the provisions of sections (2), (3), (4) and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in section (1) of this rule applies only to industrial products or devices that have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to OAR 333-102-0235 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State that authorizes manufacture of the products or devices for distribution to persons granted a general license by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by section (1) of this rule must apply for registration of the general license pursuant to OAR 333-101-0007, and submit the required fee pursuant to 333-103-0015. Applicants will receive a validation certificate from the Department. Application for registration must be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

(a) The general licensee must provide the following information in accordance with the registration application required by OAR 333-101-0007 and such other information as may be required by that form:

(A) Name and address of the general licensee;

(B) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in section (1) of this rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in subsection (3)(b) of this rule.

(b) The general licensee possessing or using depleted uranium under the general license established by section (1) of this rule must report any changes in information in writing to the Department within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by section (1) of this rule:

(a) Must not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) Must not abandon such depleted uranium;

(c) Must transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of OAR 333-102-0330. In the case where the transferee receives the depleted uranium pursuant to the general license granted by section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by OAR 333-101-0007. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by OAR 333-101-0007 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule;

(d) Must report in writing to the Department, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) Must not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to the depleted uranium covered by that general license.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; 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

General Licenses -- Radioactive Material Other than Source Material

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)** ~~500 microcuries (18.5 MBq)~~ 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)** ~~500 microcuries (18.5 MBq)~~ of polonium-210 per device or a total of not more than **1.85 GBq (50 millicuries)** ~~50 millicuries (1.85 GBq)~~ 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~~Department.]

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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

333-102-0110

Luminous Safety Devices for Aircraft

(1) A general license is hereby granted 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 ~~370 GBq (10 curies)~~~~10 curies (370 GBq)~~ of tritium or ~~11.1 GBq (300 millicuries)~~~~300 millicuries (11.1 GBq)~~ of promethium-147; and

(b) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the ~~Agency~~Department, or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32.53.

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(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in section (1) of this rule are exempt from the requirements of divisions 111 and 120 of this chapter except that they must comply with the provisions of 333-120-0700 and 333-120-0710.

(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 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), 333-100-0065 (Tests), 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 division 118 of this chapter.

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

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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

333-102-0115

Certain Measuring, Gauging and Controlling Devices

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR 333-103-0015 and sections (2), (3) and (4) of this rule, radioactive material, excluding special nuclear material, contained in devices

designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in section (1) of this rule applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Department pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.

(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(h) of this rule.

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 21 CFR 179.21.

(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:

(a) Must 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 must comply with all instructions and precautions provided by such labels;

(b) Must 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) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:

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

(B) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.

(d) Must maintain records showing compliance with the requirements of subsections (4)(b) and (4)(c) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:

(A) Records of tests for leakage of radioactive material required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(B) Records of tests of the on-off mechanism and indicator required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.

(C) Records which are required by subsection (4)(c) of this rule must be maintained as required in OAR 333-100-0057;

(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 microcurie (185 Bq) or more of removable radioactive material, the licensee must immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more 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, must be submitted to the Department within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Department, on a case-by-case basis;

(f) Must not abandon the device containing radioactive material;

(g) Except as provided in subsection (4)(h) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(k) of this rule, by transfer to another general licensee as authorized in subsection (4)(h) of this rule, or by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes the individual to receive the device; and

(A) Must furnish to the Department, within 30 days after transfer of a device to a specific licensee or export, a report containing identification of the device by manufacturer's name, model number, serial number, the date of transfer, and the name, address and license number of the person receiving the device;

(B) The general licensee must obtain written Department approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.

(h) -A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

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

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label so that the device is labeled in compliance with OAR 333-120-0430, however the manufacturer model and serial numbers must be retained;

(C) Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures);

(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).

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(ih) Must transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor must give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the date of transfer, the name and address of the transferee and the location of use, and the name, title and phone number of the individual who is a point of contact between the Department and the transferee. This individual must have the knowledge and authority to take actions to ensure compliance with the appropriate rules and requirements concerning the possession and use of these devices; or

(B) 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.

(ji) Must comply with the provisions of OAR 333-120-0700 and 333-120-0710 for reporting radiation incidents, theft or loss of licensed material but shall be exempt from the other requirements of divisions 111 and 120 of this chapter;

(kj) Must submit the required Department form and receive from the Department a validated registration certificate acknowledging the general license and verifying that all provisions of these rules have been met. The form must be submitted within 30 days after

the first receipt or acquisition of such device. The general licensee must develop and maintain procedures designed to establish physical control over the device as described in this rule and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices.

(~~1k~~) Shall not export a device containing radioactive material except in accordance with 10 CFR Part 110.

(5) The general license in section (1) of this rule does not authorize the manufacture of devices containing radioactive material.

(6) The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0335, 333-103-0015 and 333-118-0050.

(7) The general licensee possessing or using devices licensed under the general license established by section (1) of this rule must report in writing to the Department any changes in information furnished by the licensee on the required Department form. The report must be submitted within 30 days after the effective date of such change.

(8) The licensee must 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, must 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.

(9)(a) A device distributed or otherwise received as a generally licensed device must be registered with the Department. Devices containing more than 37 MBq (1 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), are required to have a specific license. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee.

(b) In registering devices, the general licensee must 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 radioisotope 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 section (8) of this rule.

(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.

(10) General licensees must report changes to their mailing address or the location of use (including a change in name of general licensee) to the Department within 30 days of the effective date of the change.

(11) Generally licensed devices that are not in use for longer than two years must be transferred to an authorized recipient or disposed of as radioactive waste. Shutters must be locked in the closed position on devices that are not being used or are in storage. The testing required by subsection (4)(b) of this rule 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.

(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in subsection (9)(a) of this rule are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.

(13) The general license in section (1) of this rule does not authorize the manufacture or import of devices containing radioactive material.

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

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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 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

333-102-0120

Ownership of Radioactive Material

A general license is hereby granted to own radioactive material without regard to quantity. Notwithstanding any other provisions of this division, this general license does

not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

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

333-102-0125

Calibration and Reference Sources

(1) A general license is hereby granted to those persons listed in subsections (1)(a) and (1)(b) of this rule to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of sections (4) and (5) of this rule, americium-241, plutonium, and/or radium-226, in the form of calibration or reference sources:

(a) Any person who holds a specific license issued by the Department that authorizes receipt, possession, use, and transfer of radioactive material; and

(b) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission that authorizes receipt, possession, use, and transfer of special nuclear material.

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

(3) A general license is hereby granted to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of sections (4) and (5) of this rule to any person who holds a specific license issued by the Department that authorizes receipt, possession, use, and transfer radioactive material.

(4) The general licenses in sections (1), (2), and (3) of this rule apply only to calibration or reference sources that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 or that have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, 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.

(5) The general licenses provided in sections (1), (2) and (3) of this rule are 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), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfers), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, and 120 of this chapter. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) Must not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) each of americium-241, of plutonium-238, plutonium-239, or of radium-226 in such sources; and

(b) Must 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, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. 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: Show 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

(c) Must not transfer, abandon or dispose of such source except by transfer to a person authorized by a specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

(d) Must 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 that might otherwise escape during storage; and

(e) Must 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.

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

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Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1085, 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

333-102-0130

General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

(1) A general license is hereby granted 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 sections (2), (3), (4), (5) and (6) of this rule, the following radioactive materials in prepackaged units 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:

(a) Iodine-125 in units not exceeding ten microcuries (370 kBq) 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 ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(c) Carbon-14, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) 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 (740 kBq) 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) Selenium-75, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;

(g) Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcuries (185 Bq) 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.

(2) A person may not receive, acquire, possess, use or transfer radioactive material under the general license granted by section (1) of this rule unless that person:

(a) Has filed the required Department application for registration pursuant to OAR 333-101-0007 and submitted the registration fee pursuant to OAR 333-103-0015 and received from the Department a validated license with certification number assigned; or

(b) Has a license that authorizes the medical use of radioactive material that was issued under OAR chapter 333 division 116.

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

(a) The general licensee must not possess at any one time, at any one location of storage or use a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 200 microcuries (7.4 MBq);

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

(c) The general licensee must use the radioactive material only for the uses authorized by section (1) of this rule;

(d) The general licensee must dispose of the mock iodine-125 reference or calibration sources described in subsection (1)(g) of this rule as required by OAR 333-120-0500 and section (6);

(e) The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. 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.

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

(a) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59 or mock iodine-125 for distribution to persons generally licensed under section (1) of this rule 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:

(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 registrant possessing or using radioactive material granted by the general license of section (1) of this rule must report in writing to the Department any changes in the information furnished on the required Department form. The report must be furnished within 30 days after the date of such change.

(6) Any person using radioactive material pursuant to the general license granted by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to radioactive material covered by that general license, except that

such persons using mock iodine-125 described in subsection (1)(g) of this rule must comply with provisions of OAR 333-120-0500, 333-120-0700 and 333-120-0710.

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

333-102-0135

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 (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the ~~Agency~~Department, or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32.

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(2) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license granted by section (1) of this rule:

(a) Must, 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 ~~Agency~~Department, the U.S. Nuclear Regulatory Commission or any other Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of OAR 333-120-0500;

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(b) Must 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 divisions 111 and 120 of this chapter except that such persons must comply with the provisions of OAR 333-120-0500, 333-120-0700, and 333-120-0710.

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

(4) 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), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfer of material), 333-102-0335 (Modification, Revocation, and Termination of Licenses) and division 118 of this chapter.

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

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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

333-102-0190

Application for Specific Licenses.

- (1) Applications for specific licenses must be filed on a form prescribed by the Department. Information contained in previous applications, statements or reports filed with the Department, 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 Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- (3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.
- (4) 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 Department and the US Nuclear Regulatory Commission as to applications for such licenses.
- (5) 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.
- (6) An application for a license to receive and possess radioactive material for the conduct of any activity that the Department 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.

(7) An application for a specific license to use 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

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

(8) 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.

(9)(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 would not exceed one rem effective dose equivalent or five rems to the thyroid; or

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

(b) One or more of the following factors may be used to support an evaluation submitted under paragraph (9)(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 would 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 would reduce the dose received;

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

(F) Operating restrictions or procedures would 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 (9)(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 should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify 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 Department 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 Department.

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

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

(L) Exercises. Provisions for conducting quarterly communications checks with 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.

(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 Department. The licensee must provide any comments received within the 60 days to the Department with the emergency plan.

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

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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

333-102-0200

General Requirements for the Issuance of Specific Licenses

An application for a specific license~~;~~ will be approved if:

- (1) The application is for a purpose authorized by the Act;
- (2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;
- (3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;
- (4) The applicant satisfies any applicable special requirements contained in divisions 102, 105, 113, 115, 116, 117, or 121 of this chapter; and
- (5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the ~~Agency~~Department determines will significantly affect the quality of the environment, the ~~Agency~~Department Manager or designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of 10 CFR, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion must be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this rule, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values. Upon a determination that an application meets the requirements of the Act, and the rules of the ~~Agency~~Department, the ~~Agency~~Department will issue a specific license authorizing the possession and use of radioactive material (Radioactive Materials License").

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(6) Financial assurance and recordkeeping for decommissioning must meet the following requirements:

(a) 10 CFR 30.35 and 30.36 for radioactive material that is not source or special nuclear material; or

(b) 10 CFR 40.36 for source material; or

(c) 10 CFR 70.25 for special nuclear material.

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

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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

333-102-0203

Definitions

The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:

NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.

(1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe, etc. samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.

(2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.

(3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not

packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by OAR 333-103-0010(2)(m)), or other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.

(4) "Beneficiating" means subjecting a product to any process that will increase or concentrate any component (including the radioactive materials) to benefit the product.

(5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with OAR 333-116-0420. Brachytherapy includes radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.

(6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.

(7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.

(8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.

(9) "Commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site.

(10) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

(11) "Decontamination and Decommissioning" means:

(a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and

(b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.

(12) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

(13) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.

(14) "Exempt Source" means radioactive material, exempt from the rules in this chapter.

(15) "Facility" means location of licensed activities under the direct control of licensee management. If a "facility," as used in this division, includes multiple separate addresses, the Department may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.

(16) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-ray & Hybrid Gauges pursuant to division 115 of this chapter, that contain either an X-ray source or a radioactive sealed source.

(17) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

(18) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0103.

(19) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.

(20) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.

(21) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.

(22) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.

(23) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.

(24) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed; conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.

(25) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.

(26) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.

(27) "Generators and Kits" means "Imaging and Localization."

(28) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.

(29) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.

(30) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an X-ray source, pursuant to division 115 of this chapter.

(31) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by OAR 333-102-0130(2).

(32) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with OAR 333-116-0320 or positron emission tomography studies in accordance with OAR 333-116-0800 through 333-116-0880.

(33) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.

(34) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.

(35) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.

(36) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.

(37) "Irradiator Self-shielded or Other -- Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.

(38) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

(39) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

(40) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.

(41) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.

(42) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (13) and (41) of this rule and require separate specific licenses for each activity.

(43) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.

(44) "Nationally Tracked Source" means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR 20 Appendix E.

(45) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05% source material.

(46) "Net working capital" means current assets minus current liabilities.

(47) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

(48) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.

(49) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.

(50) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(n) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR 345-050. Any material that contains NORM requires a specific license unless exempted in OAR 345-050. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.

(51) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).

(52) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.

NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since

the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license should specify which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.

(53) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).

(54) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.

(55) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.

NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).

(56) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by OAR 333-116-0800 and included in the facility specific license issued pursuant to OAR 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.

(57) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.

(58) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.

(59) "Principal Activities" means activities authorized by the license that 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.

(60) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (e.g., breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").

(61) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).

(62) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.

(63) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to OAR 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.

(64) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with OAR 333-116-0360.

(65) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.

(66) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in OAR 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to OAR 333-103-0010 and 333-103-0015.

(67) "Responsible Representative" means

(a) The person designated as having responsibility for general license device or general license material;

(b) The person management has selected to certify general license inventory; and

(c) The individual responsible to the Department and to management to ensure that all regulatory elements are adequate.

(68) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.

NOTE: The Department no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.

(69) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(70) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with OAR 333-116-0400.

(71) "Special Nuclear Material" means:

(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

(72) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be annotated on the specific license, and validated with a specific license fee pursuant to OAR 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").

(73) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

(74) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets would not include intangibles such as goodwill and rights to patents or royalties.

(75) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

(76) "Temporary Job Site" means any location, where specific license material is used that is either:

(a) Not the specific location of the licensee if an in-state licensee; or

(b) Any location in the State if an out-of-state specific licensee pursuant to a specific radioactive materials license.

NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.

(77) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

(78) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to Agencies in the Department of Human Services.

(79) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in OAR 333-116-0300 for uptake, dilution, and excretion studies.

(80) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.

NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.

(81) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to OAR 333-116-0280;

(82) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.

(83) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.

NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; 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

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 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 Department, 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)

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.

(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 Department will consider information that includes, but is not limited to:

- (a) Primary containment (source capsule);
- (b) Protection of primary containment;
- (c) Method of sealing containment;
- (d) Containment construction materials;
- (e) Form of contained radioactive material;
- (f) Maximum temperature withstood during prototype tests;
- (g) Maximum pressure withstood during prototype tests;
- (h) Maximum quantity of contained radioactive material;
- (i) Radiotoxicity of contained radioactive material; and
- (j) Operating experience with identical 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 OAR 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 OAR 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 OAR 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 OAR 333-102-0115;

(c) Report to the Department 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 and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity 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 OAR 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 ~~Agency~~ **Department**, 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 OAR 333-102-0235(4)(d) of this rule, including each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model 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 Department;

(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 should show the date of each transfer,

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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~~Department.]

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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

**Special Requirement for a Specific License to Manufacture,
Assemble, Repair or Distribute Commodities,
Products or Devices Which Contain Radioactive Material**

333-102-0245

**Introduction of Radioactive Material in Exempt Concentrations into Products or
Materials, and Transfer of Ownership or Possession: Requirements for License**

An application for a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another and the

transfer of ownership or possession of the product or material containing the radioactive material: will be approved if the applicant:

(1) Satisfies the general requirements specified in OAR 333-102-0200, **provided however, that the requirements of 333-102-0200(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product;**

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

(3) Provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in 10 CFR Part 30.70 Schedule A, that reconcentrating of the radioactive material in concentrations exceeding those in 10 CFR Part 30.70 Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 10 CFR Part 30.14 or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to 10 CFR Part 32.11, or the general license provided in 10 CFR Part 150.20 (reciprocity).

(5) Each person licensed under this rule must maintain records of transfer of material and file reports with the Department as required in OAR 333-102-0247.

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

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 14-2008, f. & cert. ef. 9-15-08

333-102-0247

Records and Material Transfer Reports

Each person licensed under OAR 333-102-0235 to initially transfer devices to generally licensed persons must comply with the requirements of this rule.

(1) The licensee must report on a quarterly basis all transfers of devices to persons for use under the general license in OAR 333-102-0115 and all receipts of devices from persons licensed under OAR 333-102-0115 to the Department.

(a) The required information for transfers to general licensees includes:

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

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

(C) The date of transfer;

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

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

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

(c) For devices received from an OAR 333-102-0115 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by an OAR 333-102-0115 general licensee, 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.

(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.

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

(2) The licensee must report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to OAR 333-102-0115 and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State Agency.

(a) The required information for transfers to general licensees includes:

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

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

(C) The date of transfer;

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

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

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

(c) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(d) If the licensee makes changes to a device possessed by a general licensee, 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.

(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 must include the license number of the specific licensee.

(g) If no transfers have been made to or from a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Department.

(3) The licensee must maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section must be maintained in accordance with OAR 333-100-0057.

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 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

333-102-0250

Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under a General License

An application for a specific license to manufacture or distribute radioactive material for use under the general license specified in OAR 333-102-0130 or equivalent will be approved if:

- (1) The applicant satisfies the general requirements specified in OAR 333-102-0200;
- (2) The radioactive material is to be prepared for distribution in prepackaged units of:
 - (a) Carbon-14 in units not exceeding ten microcuries (370 kBq) each;
 - (b) Cobalt-57 in units not exceeding ten microcuries (370 kBq) each;
 - (c) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each;
 - (d) Iodine-125 in units not exceeding ten microcuries (370 kBq) each;
 - (e) Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each;
 - (f) Iodine-131 in units not exceeding ten microcuries (370 kBq) each;
 - (g) Iron-59 in units not exceeding 20 microcuries (740 kBq) each;
 - (h) Selenium-75 in units not exceeding ten microcuries (370 kBq) 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 ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(b) Displaying the radiation caution symbol described in OAR 333-120-0400 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 U.S. 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 in OAR 333-120-0500.

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; 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

333-102-0255

Licensing the Distribution of Radioactive Material in Exempt Quantities

(1) An application for a specific license to distribute NARM to persons exempted from these rules pursuant to OAR 333-102-0035 will be approved if:

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

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

(c) The applicant submits copies of prototype labels and brochures and the ~~Agency~~Department approves such labels and brochures.

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(2) The license issued under this rule is subject to the following conditions:

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

(b) Each exempt quantity must be separately and individually packaged. No more than ten such packaged exempt quantities must be contained in any outer package for transfer to persons exempt pursuant to OAR 333-102-0035. The outer package must be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 microSv) per hour;

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

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

(B) Bears the words Radioactive Material.

(d) In addition to the labeling information required by section (2)(c) of this rule, the label affixed to the immediate container, or an accompanying brochure, must:

(A) State that the contents are exempt from Licensing State requirements;

(B) Bear the words, Radioactive Material -- Not for Human Use -- Introduction into Foods, Beverages, Cosmetics, Drugs or Medicinals or into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not Be Combined; and

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

(3) Each person licensed under this rule must maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under OAR 333-102-0035 or the equivalent rules of any Agreement State or Licensing State and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license must be filed with the ~~Agency~~Department. Each report must cover the year ending June 30, and must be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this rule during the reporting period, the report must so indicate.

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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.

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

333-102-0260

Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under OAR 333-102-0025 will be approved if the application satisfies requirements equivalent to those contained in section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device must not exceed 0.1 microcurie (3.7 kBq).

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

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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

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~~Department.]

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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

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~~Department.]

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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

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~~Department.]

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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

333-102-0285

Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter will be approved if:

- (a) The applicant satisfies the general requirements specified in OAR 333-102-0200;
- (b) The applicant submits evidence that the applicant is at least one of the following:
 - (A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
 - (B) Registered or licensed with a ~~S~~state ~~agency~~Department as a drug manufacturer;
 - (C) Licensed as a pharmacy by a State Board of Pharmacy; or
 - (D) Operating as a nuclear pharmacy within a Federal medical institution.

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

(d) The applicant satisfies the following labeling requirements:

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:

(a) May prepare radioactive drugs for medical use, as defined in OAR 333-116-0020, provided that the radioactive drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(c) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

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

(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

(B) This individual meets the requirements specified in OAR 333-116-0910 and 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(c) of this rule.

(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in OAR 333-116-0020 as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the Department pursuant to this division.

(e) Must provide to the Department a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(b)(A) and (C) of this rule, the individual to work as an authorized nuclear pharmacist.

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

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

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

(4) Nothing in this rule relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

NOTE: Although the ~~Agency~~Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the ~~Agency~~Department for use by persons licensed for medical use pursuant to OAR 333-116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory Commission or any other Agreement State, may submit the pertinent information specified in this rule.

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

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

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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

333-102-0290

Manufacture and Distribution of Sources or Devices Containing ~~By Product~~ Radioactive Material for Medical Use

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(1) An application for a specific license to manufacture and distribute sources and devices containing ~~byproduct~~~~radioactive~~ 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 and 333-116-0420 will be approved if:

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- (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.

(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 ~~Agency~~Department will consider information that includes, but is not limited to:

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- (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

333-102-0293

Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

(1) An application for a specific license to manufacture industrial products or devices containing depleted uranium for use pursuant to OAR 333-102-0103 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

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

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in OAR 333-120-0100; and

(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under this rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Department may deny any application for a specific license under this rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to section (1) of this rule must:

(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device; and in the installation of the depleted uranium into the product or device;

(b) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

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

(A) Furnish a copy of the general license contained in OAR 333-102-0103 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in OAR 333-102-0103; or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to OAR 333-102-0103 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in OAR 333-102-0103 to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in OAR 333-102-0103.

(d) Report to the Department all transfers of industrial products or devices to persons for use under the general license in OAR 333-102-0103. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons granted a general license by OAR 333-102-0103 during the reporting period, the report must so indicate.

(e) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 40.25 of 10 CFR Part 40.

(A) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to OAR 333-102-0115 for use under a general license in that state's regulations equivalent to OAR 333-102-0103.

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

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

(f) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon the request of that Agency.

(g) Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in OAR 333-102-0101(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records must be maintained until inspection by the Department and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of section (9) of this rule.

(h) Licensees required to submit emergency plans by OAR 333-102-0190(9) must follow the emergency plan approved by the Commission. The licensee may change the plan without Commission approval if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Department.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; 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

333-102-0297

Sealed Source or Device Evaluation

No sealed source or device containing radioactive material may be authorized on a specific license or general license until radiation safety information for that sealed source or device has been evaluated by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0300

Issuance of Specific Licenses

(1) Upon a determination that an application meets the requirements of the Act and these rules, the ~~Agency~~**Department** will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

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

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

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

(c) Prevent loss of theft of material subject to this division.

(3) Whenever the ~~Agency~~**Department** denies an application for a new license or a license renewal, the ~~Agency~~**Department** will notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to OAR 333-102-0345.

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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

333-102-0305

Specific Terms and Conditions of License

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the ~~Agency~~**Department**.

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(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the

~~AgencyDepartment~~, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

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(3) Each person licensed by the ~~AgencyDepartment~~, pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

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(4) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, As Amended, whether or not these provisions are expressly set forth in the license.

(5) The ~~AgencyDepartment~~ may incorporate, in any license issued pursuant to pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:

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(a) Promote the common defense and security;

(b) Protect health or to minimize danger to life or property;

(c) Protect restricted data;

(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(6) Licensees required to submit emergency plans by OAR ~~333-102-0190(9)~~ ~~333-102-0200(10)~~ must follow the emergency plan approved by the ~~AgencyDepartment~~. The licensee may change the approved plan without ~~AgencyDepartment~~ approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the ~~AgencyDepartment~~ and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the ~~AgencyDepartment~~.

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(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators must test the generator eluates for molybdenum-99

breakthrough in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made.

(8)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the ~~Agency~~Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

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(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101 (14)) controlling the licensee or listing the license or licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.

(b) This notification must indicate:

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

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

(9) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee.

(10) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(11) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210.

(12) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by section (12) of this rule must be kept until inspection by the ~~Agency~~Department.

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(13) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material."

(14) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by section (14) of this rule must be kept until inspection by the ~~Agency~~Department.

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(15) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources.

(16) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer

(17) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the ~~Agency~~Department, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection ~~Services Section~~. ~~Agency~~.

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(18) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report.

(19) Testing for Leakage or Contamination of Sealed Sources must be in accordance with requirements in OAR 333-120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested.

(20) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180.

(21) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

(22) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license.

(23) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste with a physical half-life of less than 65 days, for decay-in-storage, before disposal in ordinary trash, provided that:

(a) Waste to be disposed of by storage-for-decay must be held for decay a minimum of ten half-lives; and

(b) Prior to disposal in ordinary trash, decayed waste must be surveyed with an instrument that will properly record background radiation dose, to confirm that the radioactivity cannot be distinguished from background. All radiation labels must be removed or obliterated; and

(c) Notwithstanding OAR 333-102-0305(23)(a) iodine-125 waste in microcurie amounts may be held for a minimum of five half-lives. Such waste must be surveyed with an appropriate instrument prior to disposal to confirm that waste is indistinguishable from background.

(24) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee.

(25) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.

(26) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

(27) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than $n+1$ where n =the number of cameras.

(28) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of ~~two~~ three independent physical controls that form tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.

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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

333-102-0310

Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas

(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.

(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:

(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(9);

(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:

(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or

(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;

(C) Specific licenses whose holders are listed in the SDMP List published in NUREG 1444, Supplement 1 (November 1995);

(D) Specific licenses who need an environmental assessment or environmental impact statement pursuant to Subpart A of Part 51 and OAR 333-102-0200(5);

(E) Specific licenses whose holders have not had at least one Department inspection of licensed activities before February 15, 1996;

(F) Specific licenses whose holders, as the result of the most recent Department inspection of licensed activities conducted before February 15, 1996, have been:

- (i) Cited for a serious health and safety noncompliance;
- (ii) Subject to an Order issued by the Department; or
- (iii) Subject to a Confirmatory Action Letter issued by the Department.

(G) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.

(2) Each specific license revoked by the Department expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee must:

- (a) Limit actions involving material to those related to decommissioning; and
- (b) Continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.

(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must 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 building or outdoor area is suitable for release in accordance with Department requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:

- (a) The license has expired pursuant to sections (1) or (2) of this rule; or
- (b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or 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 Department requirements; or

(c) No principal activities under the license have been conducted for a period of 24 months; or

(d) No principal activities have been conducted for a period of 24 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 Department requirements.

(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. 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 paragraph (7)(d)(E) of this rule.

(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.

(b) 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.

(6) The Department may grant a request to extend the time periods established in section (4) of this rule 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 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Department has made a determination on the request.

(7)(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:

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

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

(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or

(D) Procedures could result in significantly greater releases of radioactive material or source 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 section (4) of this rule 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 subsection (7)(a) of this rule 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:

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

(B) A description of planned decommissioning activities;

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

(D) A description of the planned final radiation survey; and

(E) 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.

(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.

(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.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(9) 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 24-month period;

(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-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.

(10) As the final step in decommissioning, the licensee must:

(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 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 10 CFR Part 20, Subpart E. The licensee must, as appropriate:

(A) Report levels of gamma radiation in units of millisieverts (microrentgen) 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 100 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

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

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

- (a) Radioactive material or source material has been properly disposed;
- (b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and
- (c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or
(B) 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 10 CFR Part 20, Subpart E.
- (d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:
 - (A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.
 - (B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.
 - (C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Department terminates each license that authorizes disposal of the material.

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

333-102-0315

Application for Renewal of Licenses

- (1) Application for renewal of a specific license must be filed in accordance with OAR 333-102-0190.
- (2) In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license

authorizing the same activities, such existing license shall not expire until final action by the ~~Department~~~~Agency~~.

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(3) Unless otherwise specified, specific licenses shall expire after five years.

(4) The ~~Agency~~~~Department~~ shall require reapplication when the license expires.

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(5) The ~~Agency~~~~Department~~ may grant, upon written request from a licensee, extension of the license expiration date up to five years from the original expiration date.

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Notwithstanding any licensee request, the ~~Agency~~~~Department~~ is not required, and may deny, any license extension, based on review of licensed activities.

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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

333-102-0320

Amendment of Licenses at Request of Licensee

Application for amendment of a license must be filed in accordance with OAR 333-102-0190 and must specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0325

~~Agency~~~~Department~~ Action on Applications to Renew and Amend

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In considering an application by a licensee to renew or amend the license, the ~~Agency~~~~Department~~ will apply the criteria set forth in OAR 333-102-0200 through 0290, as applicable.

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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; PH 4-2007, f. & cert. ef. 3-1-07

333-102-0327

Specifically Licensed Items -- Registration of Product Information

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be made in duplicate and sent to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

NOTE: The U.S. Nuclear Regulatory Commission charges a fee for processing a sealed source or device evaluation request. Contact the U.S. Nuclear Regulatory Commission directly for current fee structure.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The U.S. Nuclear Regulatory Commission normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. The U.S. Nuclear Regulatory Commission uses criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(5) After completion of the evaluation, the U.S. Nuclear Regulatory Commission, issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

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

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

(b) The provisions of the registration certificate.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: 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

333-102-0330

Transfer of Material

(1) No licensee may transfer radioactive material except as authorized pursuant to this rule.

(2) Except as otherwise provided in the license and subject to the provisions of sections (3) and (4) of this rule, any licensee may transfer radioactive material:

(a) To the Department;

NOTE: A licensee may transfer radioactive material to the Department only after receiving prior approval in writing from the Department.

(b) To the U.S. Department of Energy;

(c) To any person exempt from the rules in this division to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, an Agreement State or a Licensing State; or

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

(3) Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by section (3) of this rule are acceptable:

(a) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(b) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(d) The transferor may obtain other information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration;

(e) When none of the methods of verification described in subsections (4)(a) through (4)(d) of this rule are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(5) Shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

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 14-2008, f. & cert. ef. 9-15-08

333-102-0335

Modification, Revocation and Termination of Licenses

(1) The terms and conditions of each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be subject to amendment, revision or modification or by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act by the Department.

(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact

or any report, record or inspection or other means that would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or of any rule, regulation or order of the US Nuclear Regulatory Commission or the Department.

(3) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(4) The Department may terminate a specific license upon request submitted by the licensee to the Department in writing.

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; PH 14-2008, f. & cert. ef. 9-15-08

333-102-0340

Reciprocal Recognition of Licenses

(1) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or a licensing state, and issued by the Department 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 180 days in any calendar year, provided that:

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

(b) The out-of-state licensee has notified the Department using the **Notification of Entry to Perform Activities Under Oregon Reciprocity** ~~Agency Reciprocity~~ Application form at least three days prior to engaging in such activity and has paid the applicable registration fee pursuant to OAR 333-103-0030. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license granted by subsection (1)(a) of this rule;

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(c) The out-of-state licensee complies with all applicable rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions that may be inconsistent with applicable rules of the Department or laws of the State of Oregon;

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

(e) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in subsection (1)(a) of this rule except by transfer to a person:

(A) Specifically licensed by the Department or by the U.S. Nuclear Regulatory Commission to receive such material; or

(B) Exempt from the requirements for a license for such material under OAR 333-102-0010(2).

(2) Notwithstanding the provisions of section (1) of this rule, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to 10 CFR 31.6 or equivalent regulations of an Agreement State, authorizing the holder of the license to manufacture, transfer, install or service a device described in OAR 333-102-0115(1) within the State of Oregon is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:

(a) Such person shall register the general license pursuant to OAR 333-101-0007;

(b) File a report with the Department within 30 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;

(c) Ensure that the device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;

(d) Ensure that any labels required to be affixed to the device under rules of the licensing authority also include the statement "Removal of this label is prohibited"; and

(e) The holder of the specific license shall furnish to each general licensee to whom such device is transferred, or on whose premises such a device is installed, a copy of the general license contained in OAR 333-102-0115 or in equivalent rules of the Department having jurisdiction over the manufacture and distribution of the device.

(3) The Department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, 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.

(4) The out-of-state licensee shall at all times during work at any work location within the state have available the pertinent licensing document, the applicable sections of the State of Oregon radiation regulations, a complete source inventory, pertinent U.S. Department of Transportation documentation, leak test records, instrument calibration records, personnel training records, and necessary documentation required by applicable special requirements of these regulations.

(5) While working in Oregon, the out-of-state licensee shall notify the Department (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (bankruptcy) of the United States code by or against:

(a) The licensee;

(b) An entity (as that term is defined in II U.S.C 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(c) An affiliate (as that term is defined in II U.S.C. 101(2)) of the licensee.

(6) The out-of-state licensee shall notify the Department within one hour after arrival at the actual work location within the state and notification within one hour after any change of work location within the state.

(7) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to this rule, each day worked at each location shall count toward the limit of 180 days in a calendar year.

(8) The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U. S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, 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.

(9) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule, based upon an acceptable licensing document, will receive acknowledgment from the Department. This acknowledgment shall be kept at the site of use.

(10) Each general licensee granted authorization to conduct activities within the state of Oregon pursuant to this rule based upon an acceptable licensing document is subject to

the reciprocity fee and may be inspected by the Department. The fee for the general license granting reciprocity shall:

- (a) Be charged as provided by division 103 of this chapter; and
- (b) Shall not be charged more often than once during each calendar year.

(11) Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20.

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 14-2008, f. & cert. ef. 9-15-08

333-102-0345

Special Procedures in Regulatory Review

(1) The provisions of ORS chapter 183 governing contested cases are applicable in any case where the Department proposes to refuse to issue, renew, modify, amend, revise, revoke or suspend a general or specific license or to find noncompliance with or to refuse to grant exemption from a regulation of the Department.

(2) In any case where the Department proposes to grant, issue, renew, modify, amend or revise a general or specific license, or to find compliance or to grant exemption from a regulation of the Department and the Assistant Director of the Public Health Division determines that such action would first merit public notice and opportunity for hearing, the following procedures shall be applicable:

(a) Notice of the proposed action shall be published in the Secretary of State's bulletin or a newspaper of general circulation in the state, which notice shall provide that within 15 days of the day of publication of the notice, any person whose interest may be affected by the outcome of the proceeding, or who represents a public interest in the results of the proceeding, may file a petition to be made a party and given an opportunity for hearing in the matter. The notice of proposed action shall set forth:

(A) The nature of the action proposed;

(B) The manner in which and the location at which inspection may be made of the Department records pertaining to the proposed action; and

(C) A reference of the Department's rules governing institution and conduct of hearings in radiation control proceedings.

(b) If no request for hearing is filed within the time prescribed in the notice, the proposed action shall be taken;

(c) If a hearing is requested, the person requesting to participate as a party must file a petition requesting party status and opportunity for hearing, setting forth the same information required of a person requesting party status in a contested case when the Department has given notice that it intends to hold a contested case hearing pursuant to OAR 137-003-0005(6). The same procedures for determining party status under OAR 137-003-0005 shall be followed upon receipt of the petition;

(d) If the Department allows party status, it shall in the same order set the time for a contested case hearing and provide notice of the order to the petitioner and all parties;

(e) A contested case shall proceed in accordance with the provisions of ORS chapter 183 governing contested cases.

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 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

333-102-0350

Reporting Requirements

(1) Immediate report. Each licensee must notify the Department as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(2) Twenty-four hour report. Each licensee must notify the Department within 24 hours after the discovery of any of the following events involving licensed material:

(a) An unplanned contamination event that:

(A) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(b) An event in which equipment is disabled or fails to function as designed when:

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(B) The equipment is required to be available and operable when it is disabled or fails to function; and

(C) No redundant equipment is available and operable to perform the required safety function.

(c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and

(B) The damage affects the integrity of the licensed material or its container.

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of this rule must be made as follows:

(a) Licensees must make reports required by sections (1) and (2) of this rule by telephone to the Department. To the extent that the information is available at the time of notification, the information provided in these reports must include:

NOTE: The 24-hour telephone number for the Department is 971-673-0490.

(A) The caller's name and call back telephone number;

(B) A description of the event, including date and time;

(C) The exact location of the event;

(D) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(E) Any personnel radiation exposure data available.

(b) Written report. Each licensee who makes a report required by sections (1) or (2) of this rule must submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be faxed or sent to the Department with Attention to Manager, Radiation Protection Services, Office of Environmental Public Health, 800 NE Oregon Street, Suite 640, Portland, OR 97232. The reports must include the following:

- (A) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
 - (B) The exact location of the event;
 - (C) The isotopes, quantities, and chemical and physical form of the licensed material involved;
 - (D) Date and time of the event;
 - (E) Corrective actions taken or planned and the results of any evaluations or assessments; and
 - (F) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.
- (4) The provisions of this rule apply to licensees subject to the notification requirements in OAR 333-102-0200(5).

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

333-102-0355

Records

(1) Each person who receives radioactive material pursuant to a license issued in accordance with the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

- (a) The licensee must retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(b) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another division of the rules in this chapter dictates otherwise.

(c) The licensee who disposed of the material must retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.

(2) The licensee must retain each record that is required by the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3)(a) Records that must be maintained pursuant to this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department rules. The record also may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.

(b) If there is a conflict between the Department's rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter for such records must apply unless the Department, pursuant to OAR 333-102-0003, has granted a specific exemption from the record retention requirements specified in the rules in this division or divisions 105, 113, 115, 116, 117, and 121 of this chapter.

(4) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must forward the following records to the program office:

(a) Records of disposals of licensed material made prior to January 28, 1981; and

(b) Records required by OAR 333-120-0620(2)(d).

NOTE: Prior to Oregon Department of Energy's Energy Facility Siting Council rules for burial of small quantities of licensed materials in soil was permitted without specific Department authorization.

(5) If licensed activities are transferred or assigned in accordance with OAR 333-102-0305(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, must 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 of licensed material made under OAR 333-120-0510 (including burials authorized before January 28, 1981), 333-120-0520, 333-120-0530, 333-120-0540; and

(b) Records required by OAR 333-120-0620(2)(d).

(6) Prior to license termination, each licensee must forward the records required by OAR 333-102-0200(6) to the Department.

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

333-102-0360

Right to Cause the Withholding or Recall of Byproduct Material

The ~~Agency~~Department may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the ~~Agency~~Department, or who uses such materials in violation of law or regulation of the ~~Agency~~Department, or in a manner other than as disclosed in the application therefore or approved by the ~~Agency~~Department.

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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 4-2007, f. & cert. ef. 3-1-07

333-102-0365

Third Party Method

If the applicant consents, the ~~Agency~~Department may enter into third party agreements for the applicant to engage and pay for the services of a third party contractor to prepare an environmental impact analysis required by OAR 333-102-0190 and/or to furnish an opinion of independent experts, satisfactory to the ~~Agency~~Department, in respect to the completeness and adequacy of any information or data furnished by the applicant and on any aspect of the applicant's project or effects thereof.

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(1) When the license applicant pays for a third party agreement, the monies paid for the consultant must not be considered as specific license fees, pursuant to OAR 333-103-0010 of this chapter.

(2) In proceeding under the third party agreement, the ~~Agency~~Department shall carry out the following practices:

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(a) Such contractor shall be chosen solely by the ~~Agency~~Department.

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(b) The ~~Agency~~Department shall manage the contract.

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(c) The consultant must be selected based on the consultant's ability and relevant and applicable work experience and an absence of conflict of interest. Third party contractors shall be required to execute a disclosure statement showing that they have no financial or other conflicting interest in the outcome of the project.

(d) The ~~Agency~~Department shall specify the information to be developed and supervise the gathering, analysis and presentation of the information. The ~~Agency~~Department shall have sole authority for approval and modification of the statement, analysis, and conclusions included in third party's report.

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(e) The ~~Agency~~Department has the single right of refusal of the final application and the ~~Agency~~Department is not obligated to approve the application or issue a license.

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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

Transport

333-102-0900

Special Requirements for Specific Licenses of Broad Scope

This rule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses.

(1) The different types of broad scope licenses are set forth below:

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

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 10 CFR, Part 30.100, Schedule A, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 30.100, Schedule A, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 30.100, Schedule A Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity;

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 10 CFR, Part 30.100, Schedule A, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 30.100, Schedule A, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 30.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.

(2) An application for a Type A specific license of broad scope will be approved if:

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

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

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

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

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

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

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

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with subparagraph (2)(c)(C)(ii) of this rule prior to use of the radioactive material.

(3) An application for a Type B specific license of broad scope will be approved if:

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

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

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

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

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

(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) Review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with subparagraph (3)(b)(B)(ii) of this rule prior to use of the radioactive material.

(4) An applicant for a Type C specific license of broad scope will be approved if:

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

(b) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(A) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(B) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and

quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(c) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

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

(a) Unless specifically authorized, persons licensed pursuant to this rule must not:

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

(B) Receive, acquire, own, possess, use or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(C) Conduct activities for which a specific license issued by the Department under OAR 333-102-0235, 333-102-0245, 333-102-0250, 333-102-0255, 333-102-0260, 333-102-0265, 333-102-0270, 333-102-0275, 333-102-0285, 333-102-0290, 333-102-0293, or chapter 333 divisions 105, 110, 113, 115, 116, or 117 is required; or

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

(b) Each Type A specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee;

(c) Each Type B specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer;

(d) Each Type C specific license of broad scope issued under this division shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of section (4) of this rule.

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-

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1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; 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

333-102-0910

Specific Terms and Conditions for Broad Licenses

(1) No licensee may use radioactive material in or on human beings or in field applications where radioactive material is released except as specifically authorized by license.

(2) Experimental animals administered radioactive materials or their products must not be used for human consumption.

(3) Licensees must conduct a physical inventory every six months to account for all radioactive material received and possessed under the license. The records of the inventories must be maintained until inspection by the Radiation Protection **Services Section Agency**, and must include the quantities and kinds of radioactive material, location of sealed sources and the date of the inventory.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 4-2007, f. & cert. ef. 3-1-07

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