Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Department of Human Services, Public Health Division 333

Agency and Division Administrative Rules Chapter Number

Edits, amendments and adoption of rules related to Radiation Protection Services

Rule Caption:

In the Matter of: Permanently amending and adopting Oregon Administrative Rules in chapter 333, divisions 102, 103,106, 119 and 120 pertaining to Radiation Protection Services (RPS).

Statutory Authority: ORS 431.925 – 431.955 and 453.605 – 453.807

Other Authority: 10 CFR Parts 1 - 50

Stats. Implemented: ORS 431.925 – 431.955 and 453.605 – 453.807

Need for the Rule(s):

The Department of Human Services, Public Health Division is proposing to amend and adopt Oregon Administrative Rules related to programs within the Radiation Protection Services; training requirements for the tanning industry and X-ray amendments to meet new or existing technology. The radiation materials licensing program is amending rules to comply with 10 CFR Parts 1-50 to meet the standards of byproduct material management. The tanning program rules are revised to outline tanning training standards for the registrant and operator. Division 103 is amended to increase radioactive materials licensing fees.

Documents Relied Upon, and where they are available:

Nuclear Regulatory Commission's RAT-2007-3, Byproduct Amendments
10 CFR Parts 1-50
Conference of Radiation Control Program Directors suggested State Regulations
Current Oregon Administrative Rules
Documents are available by contacting Todd Carpenter @ (971) 673-0500 or by email @ Todd.s.carpenter@state.or.us

Fiscal and Economic Impact:

Division 103 will direct radioactive materials licensing fees to be increased 20% to cover current and future expenditures. No single fee will exceed $3,000 without future legislative approval.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

   Amendments to two divisions could influence operational cost to the tanning and radioactive material industry. The radiological industry is a mixture of small and large businesses using radioactive materials for the purposes of medical research, soil studies, medical diagnostics and medical care. Division 103 will increase radiological material fees approximately 20%. A portable nuclear gauge licensee providing data for soil compaction studies would have their current fee of $612.00 adjusted to $736.00, an increase of $124.00. Division 119 may increase expenditures relating to more stringent operator training requirements designed to protect public health. Division 103 will increase fees approximately 20%. Oregon's requested fee increase will remain regionally comparable and less than 50% of similar licensing fees charged by the U.S. Nuclear Regulatory Commission in non-Agreement states. In addition they also charge full costs for all inspection and enforcement site visits to licensees. Oregon's licensees should not experience a major impact to operational expenses.

2. Cost of compliance effect on small business (ORS 183.336): (ORS 183.310(10)

Tanning registrants will need to adhere to new training requirements. Oregon is establishing a list of training vendors to assist registrants with training options. A new option being introduced is to allow online web based training to minimize travel and employee salaries paid for training time.

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

Approximately 697 tanning businesses will be affected and approximately 306 radioactive materials licensees meet the definition of "small businesses".

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services: Recordkeeping for tanning operator training will have minimal effect on the registrant's administrative services to maintain training records. This is currently required by Oregon's Administrative Rule.

c. Equipment, supplies, labor and increased administration required for compliance: Radiation Protection Services have the programs in place for regulatory and registration oversight. No significant cost related to labor, capital expenditures or supplies are foreseen with these revisions.

How were small businesses involved in the development of this rule? Through a Notice to Interested Parties, and affected industries were represented on the Radiation Advisory Committee.

Administrative Rule Advisory Committee consulted?: YES – Please list the organizations that were represented.

Industrial radioactive materials licensees
Academia radioactive material licensees
Oregon Dental X-ray industry registrants
Oregon tanning business owners.

If not, why?:

Brittany Sande, Administrative Rules Coordinator

Signature | Printed name | Date

Secretary of State

*NOTICE OF PROPOSED RULEMAKING HEARING**

A Statement of Need and Fiscal Impact accompanies this form.

Department of Human Services, Public Health Division	333
Agency and Division	Administrative Rules Chapter Number

Brittany Sande	800 NE Oregon St., Suite 930, Portland, Oregon 97232	971-673-1291
Rules Coordinator	Address	Telephone

RULE CAPTION

Edits, amendments and adoption of rules related to Radiation Protection Services

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

June 22, 2010	9:00 AM	800 NE Oregon St. Room 1E; Portland, OR 97232	Jana Fussell
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

ADOPT: 333-102-0032, 333-120-0545

AMEND: 333-102-0001, 333-102-0015, 333-102-0025, 333-102-0030, 333-102-0035, 333-102-0115, 333-102-0125, 333-102-0190, 333-102-0250, 333-102-0285, 333-102-0305, 333-102-0340, 333-102-0900, 333-103-0003, 333-103-0010, 333-103-0015, 333-103-0030, 333-103-0035, 333-103-0050, 333-106-0005, 333-106-0055, 333-106-0325, 333-119-0010, 333-119-0020, 333-119-0060, 333-119-0080, 333-119-0120, 333-119-0200,333-120-0015, 333-120-0500, 333-120-0550

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth. : ORS 431.925 - 431.955 and 453.605 - 453.807

Other Auth.: 10 CFR Parts 1 through 199

Stats. Implemented: ORS 431.925 - 431.955 and 453.605 - 453.807

RULE SUMMARY

The Department of Human Services, Public Health Division, Radiation Protection Services Section is proposing to permanently adopt and amend Oregon Administrative Rules (OAR) in chapter 333, divisions 102, 103, 106, 116, 119 and 120 related to radiation protection. Changes to the OARs are necessary to comply with the Nuclear Regulatory Commission's (NRC) Code of Federal Regulations (CFR); Adopt, revise and repeal rules to comply with implemented CFRs for compatibility with NRC regulations per the state agreement; Amend division 103 to increase radioactive material licensing fees by 20% and change annual fees to assigned quarterly invoice dates to licensees; Division 106 rules are being revised to address new and emerging technology; and. Division 119 is being revised to address tanning operator training within the industry.

The Department requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.

End of business day June 25, 2010 by 5:00 p.m.

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

Brittany Sande, Administrative Rules Coordinator

Signature | Printed name | Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-20

Underlined text is being added. ~~Strikethrough text~~ is being deleted.

OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

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 byproduct material~~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 Department actions pursuant to OAR 333-100-0035 or 333-100-0040.
(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 Department may engage the services of qualified persons in order to assist the 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).

(7) Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the 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.
(8) Each applicant or licensee must notify the 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 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 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 Department by other reporting or updating requirements.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.625 - 453.807

Exempt Items

333-102-0015
Certain Items Containing Radioactive Material
(1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these rules to the extent that he or she receives, possesses, uses, transfers, owns or acquires the following products:
NOTE: Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
(a) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
(A) 25 millicuries (925 MBq) of tritium per timepiece;
(B) Five millicuries (185 MBq) of tritium per hand;
(C) 15 millicuries (555 MBq) of tritium per dial (when used, bezels must be considered as part of the dial);
(D) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;
(E) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;
(F) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (when used, bezels must be considered as part of the dial);
(G) 0.15 microcurie (5.55 kBq) of radium per timepiece;
(H) 0.03 microcurie (1.11 kBq) of radium per hand;
(I) 0.09 microcurie (3.33 kBq) of radium per dial (when used, bezels must be considered as part of the dial);

(J) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
(i) For wrist watches, 0.1 millirad (one Gy) per hour at 10 centimeters from any surface;
(ii) For pocket watches, 0.1 millirad (one Gy) per hour at one centimeter from any surface; and
(iii) For any other timepiece, 0.2 millirad (two Gy) per hour at 10 centimeters from any surface.
(K) One microcurie (37 kBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007. ~~timepieces acquired prior to June 1, 1977.~~
(b) Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before December 17, 2007;
(c) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before December 17, 2007;
(d) Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:
(A) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
(B) One microcurie (37 kBq) of cobalt-60;
(C) Five microcuries (185 kBq) of nickel-63;
(D) 30 microcuries (1.11 MBq) of krypton-85;
(E) Five microcuries (185 kBq) of cesium-137; or
(F) 30 microcuries (1.11 MBq) of promethium-147.
(G) And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 Gy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.
NOTE: For purposes of, subsection (1)(d) of this rule "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.
(e) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
(A) Each source contains no more than one exempt quantity set forth in 10 CFR Part 30.71 Schedule B; and
(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR Part 30.71 Schedule B provided that the sum of such fractions must not exceed unity.
(C) For americium-241, 0.05 microcuries (1.85 kBq) is considered an exempt quantity under paragraph~~section~~ (1)(e)(B~~8~~) of this rule.
(i) Ionization chamber smoke detectors containing not more than one microcurie (uCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.
(2) The exemptions contained in this rule must not authorize any of the following:

(a) The manufacture of any product listed;
(b) The application or removal of radioactive luminous material to or from meters and timepieces or hands and dials therefore;
(c) The installation into automobile locks of illuminators containing tritium or promethium-147 or the application of tritium to balances of precision or parts thereof;
(d) Human use, or the use in any device or article, except timepieces, which is intended to be placed on or in the human body;
(e) As applied to radioactive material exempted under section (1) of this rule, the production, packaging, repackaging or transfer of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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 byproduct ~~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 10 CFR Parts~~section~~ 32.26 of ~~10 CFR Part 32~~; or a Licensing State pursuant to OAR 333-102-0260, which authorizes the transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a s~~S~~tate under comparable provisions to OAR 333-102-0260 authorizing distribution ~~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.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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 and 124 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in self-luminous products designed to protect life or property from fires and airborne hazards provided that the products containing radioactive material must have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to OAR 333-102-0265, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
NOTE: Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
(2) 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.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0032
Self Luminous Products Containing Radium-226
(1) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of sections (1), (2), and (3) of this rule, radium-226 contained in the following products manufactured prior to November 30, 2007.
(a) Antiquities originally intended for use by the general public. For the purposes of this subsection, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(b) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.
(c) Luminous items installed in air, marine, or land vehicles.
(d) All other luminous products provided that no more than 100 items are used or stored at the same location at any one time.
(e) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this subsection~~paragraph~~, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Nuclear Regulatory Commission.
(2) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in section (1) of this rule are exempt from the provisions of the rules in this division and in divisions 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.
(3) Any person who acquires, receives, possesses, uses or transfers byproduct material in accordance with the general license in section (1) of this rule:
(a) Shall notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Department within 30 days.
(b) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to 10 CFR Part 20.2008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Nuclear Regulatory Commission.
(c) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.
(d) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any f~~F~~ederal or s~~S~~tate solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific licensee or equivalent regulations of an Agreement State, or as otherwise approved by the Department.
(e) Shall respond to written requests from the Department to provide information relating to the general licensee within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by a written authorization to the Department
(f) The general license in section (1) of this rule does not authorize the manufacture, assembly, disassembly, repair or import of products containing radium-226, except that timepieces may be disassembled and repaired.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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333-102-0035
Exempt Quantities
(1) Except as provided in sections (2), (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 byproduct ~~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 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.
(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.
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.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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)(i) 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)(i) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(l) of this rule, by transfer to another general licensee as authorized in subsection (4)(i) 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); and
(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).
(i) 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.
(j) 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;
(k) 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.
(l) 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. 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. 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, 3.7 MBq (0.1 mCi) of radium 226 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label 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.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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) Each license issued under this rule shall affix to each source or source storage container a label containing sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement thatwhich contains the information called for in the following statement: ~~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) or (RADIUM 226) 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.
(7) Each licensee licensed under the provisions of 10 CFR Part 32.57 shall perform a dry wipe test as outlined in 10 CFR Part 32.59.
[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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) Each applicant for a specific license is required to have a permanent in-state office with a copy of all required records available for inspection by the Department.
(5) An application for a license filed pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with rules of the Department and the US Nuclear Regulatory Commission as to applications for such licenses.
(6) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. No fee will be required to accompany an

application for renewal or amendment of a license, except as provided in OAR 333-103-0010.
(7) An application for a license to receive and possess radioactive material for the conduct of any activity that the 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.
(8) 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 for a source or a device containing radium-226 or accelerator-produced radioactive material with a s~~S~~tate under provisions comparable to 10 CFR Parts 32.210; or
(b) Contain the information identified in 10 CFR Part 32.210(c).
(c) Sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Nuclear Regulatory Commission or an Agreement State which the applicant is unable to provide all categories of information specified in 10 CFR Part 32.210(c) the applicant must provide:
(A) All available information identified in 10 CFR Part 32.210(c) concerning the source and if applicable the device;
(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Information must include a description of the source or device, description of radiation safety features, intended use and associated operating experience and the results of a recent leak test.
(9) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:
NOTE: If a renewal application was submitted on or before July 27, 1990, the decommissioning information may follow the renewal application but must be submitted prior to the license being issued.
(10)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:
(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials 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 (10)(a)(A) of this rule:

(A) The radioactive material is physically separated so that only a portion could be involved in an accident;
(B) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
(C) The release fraction in the respirable size range 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 (10)(a)(B) of this rule must include the following information:
(A) Facility description. A brief description of the licensee's facility and area near the site.
(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.
(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.
(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.
(G) Responsibilities. A brief description of the responsibilities of licensee personnel 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.
(N) An application from a medical facility, educational institution, or f~~F~~ederal facility to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or d~~D~~ivision 116 of this chapter or equivalent Agreement State requirements shall include:
(i~~1~~) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.
(ii~~2~~) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2).
(iii~~3~~) Identification of individual(s) authorized to prepare the PET radiopharmaceutical drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in OAR 333-116-0880 and OAR 333-116-0910.
(iv~~4~~) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.

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

(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the 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.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

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

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;

(i) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) 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 or; and colbalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) 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

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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

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 state agency 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.
(E) A Positron Emission Tomography (PET) drug production facility registered with a s~~S~~tate agency.
(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, 333-116-0760, 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:
(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and
(B) The individual practiced at a pharmacy at a gGovernment agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulator Commission. ~~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)~~(e)~~ Shall provide to the Department:
(A) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910 with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or
(B) The Commission or Agreement State license; or
(C) Commission master materials licensee permit; or

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

(E) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a gGovernment agency or fFederally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) A copy of the sState pharmacy licensure or registration no later than 30 days after the date that the licensee allows pursuant to paragraphs (2)(b)(B) and (2)(b)(C) ~~subsection ()~~ of this rule which allows the individual to work as an authorized nuclear pharmacist.

~~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 DepartmentAgency 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 DepartmentAgency 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.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0305

Specific Terms and Conditions of License

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(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, ~~and~~ 121 and 124 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 Department.
(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 Department, 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.
(3) Each person licensed by the Department 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.
(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 Department may incorporate, in any license issued 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:
(a) Promote the common defense and security;
(b) Protect health or to minimize danger to life or property;
(c) Protect restricted data; and
(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) must follow the emergency plan approved by the Department. The licensee may change the approved plan without Department approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Department 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 Department.
(7) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85, respectively, 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.

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(8)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any cChapter of Title 11 (Bankruptcy) of the United States Code by or against:
(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 Department.
(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 Department.
(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 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.
(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 10 half-lives;
(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 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.
(29) ~~(1)~~ Authorization under OAR 333-102-0190 (10)(c)(N) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other f~~F~~ederal, and s~~S~~tate requirements governing radioactive drugs.
(30~~2~~) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:
(a) Satisfy the labeling requirements in OAR 333-116-0220 for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
(b) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-116-0165.
(31) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:
(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; ~~,~~ or
(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.
(32~~4~~) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of OAR 333-116-0910.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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 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;
(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.~~
(4~~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 c~~C~~hapter of Title 11~~I~~ (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 license.
(5~~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.
(6~~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.
(7~~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.
(8~~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.
(9~~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.
(10~~1~~) 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

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 3~~0~~.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 3~~0~~.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 3~~0~~.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 3~~0~~.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 3~~0~~.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 3~~0~~.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.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 103

FEES

333-103-0003
Definitions
As used in this division, the following definitions apply:
(1) "License" ("Acknowledgment of Validation," "Validation Certificate," "Certificate of Validation") means the document issued that validates receipt of payment for a specific license or registration fee.
(2) "Registration Fee" means:
(a) The fee paid to the Department for a license for Radiation Producing Machines; or
(b) The fee paid to the Department to validate a general license registration issued pursuant to OAR 333-102-0101, 333-102-0103, 333-102-0115, 333-102-0130, or 333-102-0340
(3) "Specific License Fee" means:
(a) The annual fee is due and payable ~~October 1~~ on or before the license expiration calendar ~~quarter~~ quarter~~of each year~~, to validate specific licenses for sources of radiation; or
(b) The fee paid upon application to the Department for an Oregon Radioactive Materials License to license specific licensed sources of radiation pursuant to OAR 333-103-0010; or
(c) The fee paid to license additional sources of radiation pursuant to OAR 333-103-0010.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0010
Annual Fee for Specific Licenses
(1)(a) Each specific license listed in section (2) of this rule, as defined in OAR 333-102-0203, shall be licensed pursuant to sections (2), (3), (4), (5), and (6) of this rule by a specific license fee.
(b) Upon written request and approval by the Department, fees for new licenses or additional sources may be prorated on a quarterly basis for the current fiscal year.
(2) Each specific license type appearing in the following fee schedule shall be licensed separately with a specific license fee as indicated:
(a) Analytical/Leak Test/Fixed X-ray Fluorescence, $~~458~~552(F);
(b) Basic License, $~~812~~976(F);
(c) Brachytherapy, $~~1,836~~2,204(F);
(d) Broad Scope A, $3,000~~3,600~~(F);
(e) Broad Scope B, $~~1,836~~2,204(F);
(f) Broad Scope C, $~~916~~1,096(F);

(g) Distribution, $~~916~~ 1,096 (F);
(h) Fixed Gauge, $~~228~~276(S);
(i) High, medium and low doserate brachytherapy, $~~2,296~~2,756(S);
(j) Imaging and Localization, $~~916~~1,096(F);
(k) In Vitro Laboratory, $~~304~~364(F);
(l) Industrial Radiography:
(A) Fixed Facility, $3,000~~3,600~~(F);
(B) Field Use, $3,000~~3,600~~(F);
(m) Instrument Calibration, $~~688~~828(S);
(n) Investigational New Drug, $~~1,376~~1,652(F);
(o) Irradiator Self-Shielded, $~~916~~ 1,096(S);
(p) Manufacturing/Compounding, $~~2,448~~2,936(F);
(q) Mobile Nuclear Medicine, $~~2,448~~2,936(F);
(r) NORM (no processing), $~~612~~736(F);
(s) Nuclear Pharmacy, $3,000~~3,600~~(F);
(t) Other Measuring Device, $~~132~~160(S);
(u) Portable Gauge:
(A) X-ray Fluorescence, $~~458~~552(S);
(B) All other portable gauges, $~~612~~736(S);
(v) Radiopharmaceutical Therapy, $~~1,376~~1,652(F);
(w) RAM/NOS Facility, $3,000~~3,600~~(F);
(x) Research & Development, $~~1,376~~1,652(F);
(y) Sealed Sources for Diagnosis, $~~458~~552(S);
(z) Source Material, $3,000~~3,600~~(F);
(aa) Special Nuclear Material (sealed), $~~916~~1,096(S);
(bb) Special Nuclear Material (unsealed), $~~2,296~~2,756(F);
(cc) Teletherapy (external beam), $3,000~~3,600~~(S);
(dd) Unique, $No Fee;
(ee) Uptake and Dilution, $~~612~~736(F);
(ff) Use of Xenon Gas, $~~612~~736(F);
(gg) Waste Packaging, $3,000~~3,600~~(F);
(hh) Well Logging, $~~1,376~~1,652(S);
(ii) Professional staff hourly rate, $94.50 per hour;
(NOTE: Hourly rate applied for review of, but not limited to, RAM/NOS license applications; cost recovery related to records research for licensing files; investigations related to incidents; and response to unlicensed facilities to identify and~~/or~~ recover unlicensed or orphaned radioactive materials.)
(jj) Disposal cost recovery fee for disposal of unlicensed radioactive materials. Cost recovery fee assessed based upon bulk disposal of combined periodic RAM waste. Under cost recovery requirements, Department may also assess estimated costs for disposal of unwanted or orphaned radioactive materials.
(NOTE: (F) means facility; (S) means source.)
(3) Each specific license validation fee shall be due and payable:
(a) On or before ~~October 1~~license expiration calendar quarter ~~of each year;~~based on the following schedule~~-~~:

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(A) Validation fees for licenses expiring June through September are due by October 1 each year.~~;~~
(B) Validation fees for licenses expiring October through December are due by January 1 each year.
(C) Validation fees for licenses expiring January through March are due by April 1 each year; and,
(D) Validation fees for licenses expiring April through June are due by July 1 each year.
(b) For each specific license source of radiation listed in section (2) of this rule for which application pursuant to OAR 333-102-0190 for an Oregon Radioactive Materials License has been made;
(c) For each additional specific license source of radiation in an amendment to an existing Oregon Radioactive Materials License pursuant to OAR 333-102-0320.
(4) A license for each specific license issued pursuant to section (3) of this rule ~~for the then or current fiscal year~~ shall be provided by the Department. The certificate of validation for the ~~then or~~ current fiscal year shall be retained by the licensee and attached to the license pursuant to requirements in OAR 333-111-0005.
(5) The specific license fee that validates specific sealed sources also validates possession of one additional sealed source during source exchange (one new source and one spent source) for a period not to exceed 30 calendar days.
(6) Sealed sources manufactured and distributed as reference sources that do not exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 are exempt from specific license fees and validation if used pursuant to a specific license listed in section (2) of this rule. The license validation fee for reference sources that exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 or reference sources authorized alone without additional licensed radioactive material shall be $976~~916~~, pursuant to subsection (2)(b) of this rule.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0015
Annual Registration Fee for General Licenses and Devices
(1) Any general license granted by the Department must be validated annually by the general license registration fee listed in section (2) of this rule, unless otherwise exempted by subsection (2)(e) of this rule. Validation must be confirmed by verifying, correcting, and~~/or~~ adding to the information provided in a request for registration received from the Department. General License registration fees as defined in OAR 333-103-0003 shall:
(a) Validate each general licensed source of radiation due October 1 of each year for sources of radiation; and
(b) Validate each new application to register general license material pursuant to OAR 333-101-0007; and
(c) Registration
(2) The general licenses appearing in the following fee schedule shall be registered on the appropriate Department form and shall be validated annually by a general license registration fee:

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(a) Each healing arts facility that uses radioactive material for In Vitro laboratory or clinical testing authorized by OAR 333-102-0130, $~~132~~160;
(b) Each radiation source in a generally licensed measuring, gauging or controlling device authorized pursuant to OAR 333-102-0115(1), $~~132~~160;
(c) For radioactive material contained in devices designed and manufactured for the purpose of producing light, except Tritium exit signs, or an ionized atmosphere that exceed the limits in OAR 333-102-0105, $~~132~~ 66 per device for the first ~~six~~12 devices after which a Basic Specific License is required.
(d) Each general licensee possessing or using depleted uranium for the purpose of providing a concentrated mass in a small volume of the product or device pursuant to OAR 333-102-0103, $~~132~~160;
(e) Each General Licensee possessing or using source material for research, development, educational, commercial or operational purposed pursuant to OAR 333-102-0101, $~~200~~240;
(f) General licenses not specifically identified in subsections (2)(a), (2)(b), (2)(c) and (2)(d) of this rule are exempt from the payment of an annual general license registration fee.
(g) Each out-of-state or NRC specific licensee granted a general license pursuant to OAR 333-102-0340 to conduct activities within the S~~s~~tate of Oregon for a period not to exceed 180 days in a calendar year must pay a registration validation fee as required by OAR 333-103-0030(6).
(h) State and local government agencies are required to register each generally licensed device but are exempt from the fees required in this rule.
(3) Notwithstanding subsection (2)(g) of this rule, the general license fee shall be due and payable on or before October 1 of each year.
(4) A certificate of validation for the then current fiscal year shall be provided by the Department. The certificate for the then current fiscal year must be retained by the licensee and attached to the general license.
(5) Upon written request and approval by the Department, fees for new licenses or additional sources may be prorated on a quarterly basis for the fiscal year.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0030
Reciprocal Recognition Fee
(1) Any radiation machine or radioactive material source brought into the state for use under reciprocity must pay a fee equal to 100 percent of the appropriate license or registration validation fee, listed in OAR 333-103-0005 or 333-103-0010, not to exceed $3,000~~3,600~~ in a year.
(2) Reciprocal fees shall be due and payable prior to entry into the state.
(3) An acknowledgment of fee payment, such as a certificate of validation, will be provided by the Department~~Agency~~. The acknowledgment of fee payment must be retained by the licensee or registrant and attached to the license or registration.
(4) Reciprocal fees shall not be transferred or refunded.
(5) Reciprocal fees shall expire 12 months from the issue date.

(6) Any use of radioactive material in Oregon pursuant to OAR 333-102-0340 exceeding 30 consecutive days or 180 calendar days shall require an application for an Oregon specific radioactive materials license pursuant to OAR 333-102-190.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0035
Fees For Radiological Analyses
(1) An individual, agency, or company that requests that the DepartmentAgency Radiation Laboratory perform radiological analyses on samples must pay a fee to the DepartmentAgency in accordance with the schedule in section (2) of this rule. The responsible individual submitting the sample(s) must first obtain a request form from the AgencyDepartment. This form contains the fee schedule and the types of radiological analyses offered. That individual must then submit the completed form along with the sample and the appropriate fee to the DepartmentAgency. The DepartmentAgency will send the results by return mail in accordance with the estimated time as per section (3) of this rule.
(2) Fee Schedule: Water Solid:
(a) Gamma Isotopic --
(A) Liquid - $206 248
(B) Solid -- $236284;
(b) Low-level Iodine-131 $212;
(c) Tritium (H-3) $92.
(3) The analyses results will be available in approximately five working days for Gamma Isotopic analyses. All other types of radiological analyses results will be available in approximately 15 working days.
NOTE: If the DepartmentAgency cannot complete the analyses according to the schedule in section (3) of this rule, the DepartmentAgency will notify the customer as soon as possible.
(4) A $100 surcharge shall be added to the fee for a one-day completion schedule for a Gamma Isotopic analysis. .
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0050
Fees for Accredited Hospital Radiology Inspectors
(1) Each accreditation for a radiology inspector shall be subject to an accreditation fee of $316264.
(2) Each accreditation issued by the Department for a radiology inspector shall be subject to a biennial renewal fee of $316264.
(3) Each accreditation shall expire in the second year on the last day of the month of issuance unless renewed.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

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OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 106

X-RAYS IN THE HEALING ARTS

333-106-0005
Definitions
As used in this division, the following definitions apply:
(1) "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.
(2) "Added Filtration" means any filtration that is in addition to the inherent filtration.
(3) "Aluminum Equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.
NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
(4) “Applications Training” means a vendor or manufacturer providing specific X-ray equipment.~~training program approved by the Department.~~
(5) "A.R.R.T." means the American Registry of Radiologic Technologists.
(6) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.
(7) "Attenuation Block" means a block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
(8) "Automatic Exposure Control (AEC)" means a device that automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Photo timer".)
(9) "Barrier" (see "Protective Barrier").
(10) "Beam Axis" means a line from the source through the centers of the X-ray fields.
(11) "Beam-Limiting Device" means a device that provides a means to restrict the dimensions of the X-ray field.
(12) "Beam Monitoring System" means a system designed to detect and measure the radiation present in the useful beam.
(13) "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.
(14) "Cephalometric Device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(15) "Certified Components" means components of X-ray systems that are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control Agency for Health and Safety Act of 1968.
(16) "Certified System" means any X-ray system that has one or more certified component(s).
(17) "Changeable Filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
(18) "Coefficient of Variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.
(19) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.
(20) “Computed radiography (CR)” means creating an X-ray image using plates consisting of a photo stimulable phosphor (PSP) that when exposed to radiation and then processed by a scanner, it provides the information to a computer for display and manipulation.
(210) "Contact Therapy System" means an X-ray system used for therapy with the tube port placed in contact with or within five centimeters of the surface being treated.
(221) "Control Panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
(232) "Cooling Curve" means the graphical relationship between heat units stored and cooling time.
(243) "Dead-Man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
(254) "Department approved instructor," means an individual who has been evaluated and approved by the Department to teach Radiation Safety.
(265) "Department approved training course" means a course of training that has been evaluated and approved by the Department.
(276) "Detector" (see "Radiation detector").
(287) "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.
(298) "Diagnostic Source Assembly" means the tube housing assembly with a beam-limiting device attached.
(3029) "Diagnostic-Type Protective Tube Housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 milliroentgens (mR) in one hour when the tube is operated at its leakage technique factors.
(310) "Diagnostic X-ray System" means an X-ray system designed for irradiation of any part of the human body or animal body for the purpose of diagnosis or visualization.
(32) “Direct Digital Radiography (DR)” means creating an X-ray image by sending signals directly from a digital image receptor to a computer for display and manipulation.
(331) "Direct Scattered Radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

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(342) "Direct supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) shall be present in the room while the individual operates the equipment.
(353) "Entrance Exposure Rate" means the exposure free in air per unit of time.
(364) "Field Emission Equipment" means equipment which uses a tube in which electron emission from the cathode is due solely to the action of an electric field.
(375) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
(386) "Fluoroscopic Benchmark" means a standard based upon the average cumulative fluoroscopic on-time normally found to be used for a specific fluoroscopic procedure at the site.
(397) "Fluoroscopic Imaging Assembly" means a subsystem in which X-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
(4038) "Fluoroscopic X-ray equipment operator" means any individual who, adjusts technique factors, activates the exposure switch or button of a fluoroscopic X-ray machine or physically positions patients or animals. Human holders, used solely for immobilization purposes (i.e. veterinarian human holders) are excluded from this rule.
(4139) "Focal Spot" means the area projected on the anode of the tube by the electrons accelerated from the cathode and from which the useful beam originates.
(420) "General Purpose Radiographic X-ray System" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
(431) "General supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s), must be immediately available by telephone, pager, or other mode of communication, to provide direction if needed or requested.
(442) "Gonad Shield" means a protective barrier for the testes or ovaries.
(45) “Hand-held unit” means a self contained X-ray machine designed so that it can be held in one or two hands to perform intra-oral radiography.
(463) "Half-Value Layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
(474) "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an Oregon licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.
(485) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.
(496) "HVL" (see "Half-value layer").
(5047) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

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(5148) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.
(5249) "Indirect supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) be readily available on facility premises when the X-ray or fluoroscopic equipment is operated.
(530) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
(541) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
(552) "Irradiation" means the exposure of matter to ionizing radiation.
(563) "Kilovolt-Peak" (see "Peak tube potential").
(574) "kV" means kilovolts.
(585) "kVp" (see "Peak tube potential").
(596) "kWs" means kilowatt second.
(6057) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
(6158) "Leakage Radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:
(a) The useful beam; and
(b) Radiation produced when the exposure switch or timer is not activated.
(6259) "Leakage Technique Factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:
(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds (mAs), or the minimum obtainable from the unit, whichever is larger.
(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.
(c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
(630) "Light Field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
(641) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.
(652) "mA" means milliampere.
(663) "mAs" means milliampere second.
(674) "Maximum Line Current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

(685) "Mobile Equipment" (see “X-ray Equipment").
(696) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and
(a) Are not specifically certified in diagnostic and/or therapeutic use of X-rays; and
(b) Are currently licensed by their respective Oregon licensing board.
(7067) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended.
(7168) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.
(7269) "Peak Tube Potential" means the maximum value of the potential difference across the X-ray tube during an exposure.
(7370) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.
(741) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
(752) "PID" (see "Position indicating device").
(763) "Portable Equipment" (see "X-ray Equipment").
(774) "Position Indicating Device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
(785) "Primary Dose Monitoring System" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.
(796) "Primary Protective Barrier" (see "Protective barrier").
(8077) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
(8178) "Protected Area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:
(a) 2 milliroentgens (mR) in any one hour; or
(b) 100 mR in any one year.
(c) See OAR 333-120-0180 for additional information.
(8279) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;

(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
(8380) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
(841) "Qualified Expert" means an individual, approved by the Department, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:
(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or
(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or
(c) Receive approval from the Department for specific activities.
(852) "Quality Control Program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The X-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.
(863) "Radiation Detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
(874) "Radiation Therapy Simulation System" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
(885) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.
(896) "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.
(9087) "Radiological Physicist" means an individual who:
(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or
(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
(c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where

the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
(9188) "Radiologist" or "Oral Radiologist" means a physician or dentist trained in the diagnostic and/or therapeutic use of X-rays and who is;
(a) Currently licensed by their respective Oregon licensing board; and
(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon.
(9289) "Radiology Physician's Assistant" (R.P.A.)/ "Registered Radiology Assistant" (R.R.A.).
(a) An R.P.A. means an American Registry of Radiologic Technologists (A.R.R.T.) technologist who has successfully completed an advanced training program and is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA).
(b) An R.R.A means an A.R.R.T. technologist who has successfully completed an advanced training program and is certified by A.R.R.T.
(930) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Radiologic Technology (OBRT).
(941) "Rating" means the operating limits as specified by the component manufacturer.
(952) "Recording" means producing a permanent form of an image resulting from X-ray photons.
(963) "Registrant," as used in this division, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans, animals or materials to the useful beam of the system and is required by the provisions contained in divisions 100 and 101 of this chapter to register with the Department.
(974) "Response Time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.
(985) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").
(996) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.
(10097) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.
(10198) "Secondary Protective Barrier" (see "Protective barrier").
(10299) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
(1030) "SID" (see "Source-image receptor distance").
(1041) "Source" means the focal spot of the X-ray tube.
(1052) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.
(1063) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.

(1074) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
(1085) "Spot-Film Device" means a device intended to transport and/or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
(1096) "SSD" means the distance between the source and the skin of the patient.
(11007) "Stationary Equipment" (see "X-ray Equipment").
(11108) "Stray Radiation" means the sum of leakage and scattered radiation.
(11209) "Technique Factors" means the conditions of operation. They are specified as follows:
(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses;
(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
(11310) "Termination of Irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
(11411) "Traceable to a National Standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
(1152) "Tube" means an X-ray tube, unless otherwise specified.
(1163) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
(1174) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
(1185) "Unprotected Area" means any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workload, exceeds any of the following limits:
(a) Two mR in any one hour;
(b) 100 mR in any seven consecutive days; or
(c) 500 mR in any one year.
(1196) "Useful Beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.
(12017) "Variable-Aperture Beam-Limiting Device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.
(12118) "Visible Area" means that portion of the input surface of the image receptor over which the incident X-ray photons are producing a visible image.
(12219) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
(1230) "X-ray Control" means a device which controls input power to the X-ray high-voltage generator and/or the X-ray tube. It includes equipment such as exposure switches

(control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.
(1241) "X-ray Equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:
(a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;
(b) "Portable equipment" means X-ray equipment designed to be hand-carried;
(c) "Stationary equipment" means X-ray equipment which is installed in a fixed location; and
(d) "Transportable" means X-ray equipment installed in a vehicle or trailer.
(1252) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of an X-ray machine, or physically positions patients or animals for a radiograph (see “Operator”).
(1263) "X-ray Field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
(1274) "X-ray High-Voltage Generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
(1285) "X-ray System" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
(1296) "X-ray Subsystem" means any combination of two or more components of an X-ray system for which there are requirements specified in this division.
(13027) "X-ray Tube" means any electron tube which is designed to be used primarily for the production of X-rays.
[ED. NOTE: Equations referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

General Requirements

333-106-0055
X-ray Operator Training
(1) The registrant shall assure that individuals who will be operating the X-ray equipment shall have adequate training in radiation safety. Adequate training in radiation safety means a minimum of 40 hours of didactic instruction for diagnostic medical X-ray equipment operators, eight hours for Grenz ray X-ray equipment operators and 20 hours for veterinary X-ray equipment operators from an Department approved training course covering the following subjects:
(a) Nature of X-rays;

(b) Interaction of X-rays with matter;
(c) Radiation units;
(d) Principles of the X-ray machine;
(e) Biological effects of X-ray;
(f) Principles of radiation protection;
(g) Low dose techniques;
(h) Applicable fFederal and sState radiation regulations including those portions of divisions 100, 101, 103, 106, 111 and 120 of chapter 333;
(i) Darkroom and film processing;
(j) Film critique; and
(k) Animal restraint training (for veterinary technologists or assistants only).
NOTE: Subsectionsjects (1)(g), (1)(i) and (1)(j) are not required for Grenz ray X-ray equipment operator training.
(2) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:
(a) Currently licensed by the Oregon Board of Dentistry as a Dentist or Dental Hygienist; or
(b) Is a Dental Assistant who is certified, by the Oregon Board of Dentistry, in radiologic proficiency; and
(c) Successfully completed didactic and clinical radiography training covering the subject areas outlined in section (1) of this rule; and
(d) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered by the Dental Assisting National Board, Inc. (DANB) and clinical radiography examination or other comparable requirements approved by the Oregon Board of Dentistry.
(3) Medical X-ray equipment operators not regulated by the Oregon Board of Radiologic Technology. In addition to the above, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Radiologic Technology must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of X-ray examinations that the individual will be performing; and
(a) Have 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer; and
(b) Must have completed the required radiation use and safety hours and a minimum of 50 hours in X-ray laboratory before X-raying a human patient.
(4) Radiation Use and Safety Instructor Qualifications. The training required in sections (1), (2) and (3) of this rule must be taught by an Department approved instructor. Approval will be based upon the following criteria:
(a) Medical use and safety instructor: An individual who is currently licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Radiologic Technology.
(b) A dental radiation use and safety instructor is an individual who has:
(A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered DANB; or

(B) Has been evaluated and approved as a qualified Dental radiation use and safety instructor by the Oregon Board of Dentistry; and
(C) Is currently licensed~~,~~ by the Oregon Board of Dentistry as a dentist; or
(D) Is a dental hygienist; or
(E) Is a dental assistant certified in Radiologic proficiency and has a minimum of two years of experience in taking dental radiographs.
(c) A veterinarian radiation use and safety instructor is an individual who is:
(A) Currently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a Radiologic Technologist by the Oregon Board of Radiologic Technology; and
(B) Has completed training specific to veterinarian radiography, including training in animal restraint; and
(C) Have a minimum of two years of experience in taking veterinary radiographs.
(d)(A) On a case by case basis, if an evaluation by the Department reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (4)(a), (4)(b) or (4)(c) of this rule or is an individual who is qualified under OAR 333-101-0230 as a Hospital Radiology Inspector; or
(B) The individual meets the requirements of a qualified expert as defined in OAR 333-100-0005(80).
(5) In addition to the requirements in sections (2), (9), (10) and (13), of this rule dental X-ray equipment operator must also satisfy any requirements established by the Oregon Board of Dentistry.
(6) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.
(7) Any diagnostic medical X-ray operator is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:
(a) Holds a current license from the Oregon Board of Radiologic Technology; or
(b) Holds a current limited permit from the Oregon Board of Radiologic Technology; or
(c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Radiologic Technology; or
(d) Is a student in an Oregon Board of Radiologic Technology approved limited permit program under a Radiologic Technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Radiologic Technology.
(8) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect supervision of a Dentist or Dental Hygienist currently licensed or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry provided that:
(a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or
(b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and

(c) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (1) of this rule; and
(d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:;
(A) The use of mannequins under indirect supervision; or
(B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and
(C) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site(s) of their clinical training and available for review by, the Department of Human Services,DHS Public Health DivisionOffice of State Public Health, inspection staff at the time of inspection.
(9) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 of these rules.
(10) The students identified in section (8) of this rule are considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of twelve (12) consecutive months.
(11) Radiation use and safety training programs approved prior to the May 1, 2005 will continue to be considered as meeting the requirements of section (1) of this rule provided they cover those portions of the Oregon Rules for the Control of Radiation indicated in subsection (1)(h) of this rule.
(12) X-ray operator training approved prior to May 1, 2005 will continue to be considered as having met the requirements of sections (1), (2) or (3) of this rule as applicable.
(13) Reciprocity. X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements listed in sections (1) or (2) of this rule, if the Department's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of sections (1) or (2) of this rule.
(14) When required by the Department, applications training must be provided to the operator before use of X-ray equipment on patients.
(aA) Records of this training must be maintained by the registrant for inspection.
(bB) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

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Fluoroscopic X-ray Systems Requirements

333-106-0325
Intraoral Dental Radiographic Systems
In addition to the provisions of OAR 333-106-0010 through 333-106-0101 of these rules, the requirements of this rule apply to X-ray equipment and facilities where intraoral

dental radiography is conducted. Requirements for extraoral dental radiographic systems are covered in OAR 333-106- 0301 through 333-106-0320 of these rules. Intraoral dental radiographic systems must meet the following requirements:
(1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:
(a) 18 cm if operable above 50 kVp; or
(b) 10 cm if operable at 50 kVp only.
(2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:
(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or
(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.
(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:
(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and
(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off " position if either position is provided;
(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
(d) Exposure termination.
(e) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed: (T) >/- 5 (Tmax – Tmin).
(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.
(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.
(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".
(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:
(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(8178)(a)(b), and the operator shall remain in that protected area during the entire exposure; and
(b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.

(c) Mobile and portable X-ray systems which are:
(A) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule;
(B) Used for less than one week at the same location, i.e., a room or suite, shall be provided with:
(i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or
(ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures; or
(iii) A full length protective apron, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand held dental intraoral X-ray machine.
(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E >/- 5 (Emax - Emin)
(6) Accuracy.
(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.
(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs on humans.
(7) Administrative Controls:
(a) Patient and film holding devices shall be used when the techniques permit;
(b) The tube housing and the PID shall not be hand-held during an exposure;
(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection (2)(a) of this rule or its updated version;
(d) All patients shall be provided with a leaded lap apron during any X-ray exposure;
(e) Dental fluoroscopy without image intensification shall not be used;
(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Department.
(8) Hand-h~~H~~eld X-ray s~~S~~ystems.
(a) Registrants must provide for security and safe storage while not in use.
(A) A report must be filed with the Department~~Agency~~ within 72 hours if the hand-held unit is lost or stolen.
(b) The image receptor used with hand-held dental X-ray systems must either be:
(A) A speed class of intra-oral film designated as "E/F, F" or faster; or
(B) A digitally acquired image (CR or DR).
(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.
(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand held unit must provide documentation to the Department~~Agency~~ of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.
(e) The hand-held unit must be capable of a minimum of 60 kVp and 2.0 mA.

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(f) Hand-held units not meeting the requirements of subsections (8)(c), (8)(d) and (8)(e) of this rule may not be sold, distributed or used in the State of Oregon.
(9) Hand-held d~~D~~ental X-ray a~~A~~dministrative c~~C~~ontrols.
(a) The operator must wear a whole body protective apron and thyroid collar of 0.25 mm of lead equivalent when using the unit.
(b) Hand-held units must meet the requirement of OAR 333-106-0045(3).
(A) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.
(B) The unit will only be operated in an enclosed room and all individuals, except the x-ray operator and the patient, will leave the room and stand behind a protective barrier during radiographic exposures.
(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(14) before using a hand-held unit.
(A) Training on the safe use of the unit shall be documented and include at a minimum:
(i)~~.~~ Proper positioning of the unit to ensure an adequate protected position;
(ii)~~.~~ Limitations on the use of position indicating devices that require longer distances to the patient's face;
(iii)~~.~~ Diagrams (ie: drawings, illustrations, schematics, etc.) of protected position and location in relationship to the unit;
(iv)~~.~~ Diagrams (ie, drawings, illustrations, schematics, etc.) of the effect of improper distance or removal of shielding device; and
(v)~~.~~ Diagrams (ie. drawings, illustrations, schematics, etc.) of common examples of improper positioning of the unit and or location of the operator.
(d) An appropriate receptor holder must be used during the X-ray exposure.
(e) A PID must be used during the X-ray exposure.
(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 119

REGISTRATION OF TANNING FACILITIES

333-119-0010
Definitions
(1) "Customer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.
(2) “Department” means the Department of Human Services of the State of Oregon.
(3) "Employee" means any individual, including a minor whether lawfully or unlawfully employed, who engages to furnish services for remuneration, financial or otherwise, subject to the direction and control of an employer and includes any individual who is required to have workers' compensation coverage.
(4) "EPA" means the U.S. Environmental Protection Agency.
(5) "FDA" means the U.S. Food and Drug Administration.
(6) "Formal Training" means a course of instruction reviewed and approved by the Department and which is conducted or presented under formal classroom conditions or online by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment. Operator training shall cover ultraviolet radiation and effects on the skin, photosensitivity, FDA and State of Oregon regulations, eye protection, and equipment maintenance.
(7) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.
(8) "Individual" means any human being.
(9) "Minor" means any individual under the age of 18.
(10) "Operator" means the person who is an employee (defined by the Oregon Occupational Safety and Health Division, Oregon Administrative Rule 437-003-0011(2)) or contractor of the tanning facility who has received a certificate from an approved formal training course and who ~~that~~ is responsible for:
(a) Determining customer's skin type;
(b) Determining the suitability for use of a tanning device;
(c) Providing information regarding the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;
(d) Assuring that all required forms are understood and properly signed by the customer;
(e) Maintaining required exposure records;
(f) Recognizing and reporting injuries or alleged injuries to the registrant;
(g) Determining the customers' exposure schedule;
(h) Setting timers which control the duration of exposure; and
(i) Instructing the customer in the proper use of protective eyewear.

(11) "Other Compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.
(12) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.
(13) "Phototherapy Device" means equipment that emits Ultraviolet radiation used by a health care professional in the treatment of disease or illness.
(14) “Program” means the Radiation Protection Services section of the Public Health Division.
(15) "Protective Eyewear" means suitable eyewear that protects the eye from Ultraviolet radiation and allows adequate vision.
(16) "Registrant" means a tanning facility registered with the Department as required by provisions of this division.
(17) "Registration" means registration with the Department in accordance with provisions of this division.
(18) "Safe Level" means not more than 50 colonies of microorganisms per four square inches of equipment surface.
(19) "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product that provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with EPA as hospital disinfectants when used at recommended dilutions and directions may be approved for sanitizing of tanning devices.
(20) "Tanning Device" means any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, Ultraviolet Lamp, tanning booth, facial unit, UVA wand, or tanning bed. "Tanning device" also means any accompanying equipment, including, but not limited to, protective eyewear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.
(21) "Tanning Facility" means any location, place, area, structure, or business that provides persons access to any tanning device.
(22) "Timers" means a device provided to terminate the exposure at a preset time interval.
(23) "Ultraviolet Radiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.
Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955

333-119-0020
Registration
(1) Prior to the operation of any tanning device used by the public for a fee or other compensation, the owner or operator shall file an application with the Department and pay applicable fee(s) in the amount and in the manner specified in OAR 333-103-0025 to register each tanning device.

(2) If the owner or operator owns or operates more than one such tanning facility, the owner or operator shall file a separate application for each such facility owned or operated.
(3) Registration application shall be made on forms furnished by the Department.
(4) A validation certificate or acknowledgement of validation will be issued by the Department.
(5) The certificate issued by the Department shall be effective for one year beginning January 1 through December 31.
(6) The certificate shall be displayed in a conspicuous open public area ~~place on the premises~~ of the tanning facility.
(7) The Department will provide an identification number that will be affixed by a Department inspector to each tanning device during the initial or follow-up facility inspection:
(a) Identification numbers shall not be removed without written permission of the Department; and
(b) Identification numbers shall not be defaced.
(8) The registrant shall notify the Department in writing before making any change that would render the information contained in the application for registration or the validation of registration no longer accurate.
(9) No registration may be transferred from one person to another person, from one tanning facility to another tanning facility, or from one tanning device to another tanning device.
(10) In the event of a change in ownership, the new owner will be required to apply for a registration of the tanning device within 30 days after taking possession of the property.
(11) Tanning facilities already in existence at the time of the effective date of this rule may continue to operate. Such facility shall be given priority in the inspection process by the Department. However, should those tanning facilities fail to meet the standards, they may be prohibited from continuing to operate until such time as they have met those standards through evaluation by the Department's inspectors or through a hearing held by the Department.
(12) Failure to properly register a tanning device is subject to the imposition of a civil penalty per ORS 431.950 and ORS 431.262.
(13) The Department may require tanning facility registrants to complete and update application forms and information concerning tanning devices. ~~.~~
Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955

Specific Requirements

333-119-0060
Warning Sign
(1) The registrant shall conspicuously post the warning sign described in section (2) of this rule within one meter (39.37 inches) of each tanning device and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the customer before operating the tanning device.
(2) The warning sign in section (1) of this rule shall meet the following requirements:

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(a)~~.~~ The sign shall be printed on paper or similar material no smaller than 8.5 inches by 11 inches. Signs are available for printing on the Department's website.
(b)~~.~~ The major sign heading shall be labeled "DANGER"~~ and the section~~ and the section entitled "FAILURE" shall be a minimum of Times New Roman, b~~B~~old with a minimum font size of 40.
(c)~~.~~ The body text shall be a minimum of Times New Roman with a minimum font size of 20. ~~use upper and lower case letters that are at least 10 millimeters and five millimeters in height, respectively, and shall have the following wording:~~

DANGER -- ULTRAVIOLET RADIATION
Follow instructions.
Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.
FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.
Medications or cosmetics may increase your sensitivity to the Ultraviolet radiation. Consult a physician before using sunlamp or tanning device if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.
If you do not tan in the sun, you are unlikely to tan from the use of this product

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955

333-119-0080
Training of Personnel
(1) The registrant shall maintain documentation to verify that all tanning device operators are adequately trained in the following:
(a) The rules of this division;
(b) Procedures for correct operation of the tanning facility and tanning devices;
(c) Recognition of injury or overexposure to Ultraviolet radiation;
(d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices;
(e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices;
(f) Emergency procedures to be followed in case of injury; and
(g) Potential photosensitizing foods, cosmetics, and medications.
(2) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.
(3) All operators of ~~currently~~ registered tanning facilities must successfully complete a Department approved tanning training course in the State of Oregon prior to commencement of tanning operations by July ~~0~~1, 2011. ~~in the State of Oregon must have completed the following staff training requirements within one year of registering with the Department:~~
(a) At least one owner, manager, or operator from each tanning facility with four or less tanning devices, shall successfully complete one of the vendor-provided formal training courses authorized by the Department.

(b) At least two operators from each tanning facility with five or more tanning devices shall successfully complete one of the vendor provided formal training courses authorized by the Department.
(c) Training of other full or part-time operators shall be by means of a Department-authorized and vendor-provided training course, or by materials received by an owner or primary operator from a Department-authorized and vendor-provided training course, or by a Department-authorized correspondence course.
(4) Staff training shall be documented by the facility owner or operator and include copies of training certificates. ~~date and time with subjects covered in the training session for all operators.~~
Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930

333-119-0120
Advertising
(1) Registrants shall not claim or distribute promotional materials that claim using a tanning device is safe, free from risk or that using the device will result in medical or health benefits. Only cosmetic claims can be promoted. ~~No person or facility shall advertise the use of any Ultraviolet A or Ultraviolet B tanning device using wording such as "Safe", "Safe Tanning", "No Harmful Rays", "No Adverse Effect", or similar wording or concepts.~~
(2) No person, in any advertisement, shall refer to the fact that such person, or such person's ~~facility,~~facility is registered with the Department pursuant to the provisions of this division, and no person shall state or imply that any activity under such registration has been approved by the Department.
(3) No person or facility shall advertise or promote tanning packages labeled as "unlimited".
(4) Tanning packages shall include the following written tanning guidelines for all clients:
(a) Initial tanning sessions (three to five) are limited to intervals of at least 48 hours between sessions to allow adequate time for melanin activation and transit to occur prior to subsequent exposures. The manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device shall be followed by tanning operators advising new clients during initial tanning sessions.
(b) After the initial (three to five) tanning exposures, tanning sessions are limited to one tanning session per 24-hour period (or one tanning session per 48 hours on tanning devices so labeled) with customers being properly advised of the manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device.
(c) Promotion of annual tanning packages shall include a written statement listing the total number of sessions allowed per person, per year (recommendations should generally not exceed two sessions per week and the maximum of 30-50 sessions per year as recommended by the International Radiation Protection Association (IRPA) and other authorities).

Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.930

333-119-0200
Vendor Responsibilities
(1) Any person who sells, leases, transfers, or lends tanning devices in this state shall notify the Department of the following within 30 days after each sale or installation:
(a) Name and address of persons who have received these devices;
(b) The manufacturer model and serial numbers of each device; and
(c) The date of transfer.
(2) No person shall make, sell, lease, transfer, lend or install tanning devices or the supplies used in connection with such devices unless such supplies and equipment when placed in operation and use, will meet the requirements of these rules.
(3) State of Oregon identification numbers shall not be removed, altered or defaced by any vendor doing business in this state, without written permission of the Department.
(4) Vendors of tanning devices, replacement lamps, sanitizers, protective eyewear, UV light measurement devices, calibration of measurement equipment, remote timer systems, computer control systems, repair or cleaning services, parts supplies, or operator training are required to apply for a license for sales, services and servicing as specified in OAR 333-101-0020. Vendor l~~L~~icense application forms will be furnished by the Department. Vendors are prohibited from providing tanning equipment installation, servicing and/or services prior to the Department issuing a licensing certificate to the vendor.
(5) Vendors providing operator training services are required to apply for a license for services as specified in OAR 333-101-0020. The Department will furnish license application forms. Prior to offering training services, vendors shall submit to the Department the following: ~~Training services vendors are required to furnish a copy of all training materials (including a sample examination) to the Department for review and comment prior to offering operator training courses. Vendors shall maintain records of course completion and test results for a period of at least three years from the date of the operator training course. A copy of the list of persons successfully completing operator training shall be furnished to the Department including the following:~~
(a) A list of qualified on-site training personnel~~al~~ including a curriculum vitae or resume outlining training experiences; ~~and~~ ~~A copy of the training materials used for the specific course offered; and~~
(b) A copy of all training materials to be used; and ~~list of qualified training personnel including training experience; and~~
(c) A copy of examinations to be used.~~A list of persons trained with test scores listed and tanning facility name and address provided; and~~
~~(d) At least one Department staff member shall be invited to attend any operator training course offered within the State of Oregon without charge.~~
(6) Upon approval, a letter will be sent to the training service vendor giving permission to offer tanning operator training within the State of Oregon. ~~Not-for-profit industry sponsored training organizations are permitted to utilize recognized industry qualified experts as adjunct instructors for specific modules of training course materials that have been reviewed and authorized by the Department.~~

(7) The Department shall be notified prior to training material revisions. The Department shall review and approve all changes made to the training materials.
(8) Vendors shall maintain records of course completion and test results for a period of at least three years from the date of the operator training course. A copy of the list of persons successfully completing operator training shall be furnished to the Department and include the following:
(a). Name of persons trained; and
(b). Individual test scores; and
(c). Associated tanning facility, name and address.
(9). The Department shall be provided access to audit any operator training courses offered within the State of Oregon without charge.

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Stat. Auth.: ORS 431.925 - 431.955
Stats. Implemented: ORS 431.925 - 431.955

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OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

333-120-0015
Definitions

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the becquerel (Bq) and the Curie (Ci). The becquerel is equal to one disintegration per second (dps) and the Curie is equal to 3.7x1010 dps.

(3) “Accelerator produced radioactive material” means any material made radioactive by a particle accelerator.

(~~4~~3) "Adult" means an individual 18 or more years of age.

(~~5~~4) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(~~6~~5) "Airborne radioactivity area" means a room, enclosure, or area in which the airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

(a) In excess of the derived air concentrations (DACs) specified in 10 CFR 20 Appendix B; or

(b) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours present in a week, and intake of 0.6 percent of the annual limit of intake (ALI) or 12 DAC hours.

(~~7~~6) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(~~8~~7) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this division as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the use of licensed materials in the public interest.

(~~9~~8) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for

intake by ingestion and by inhalation of selected radionuclides are given on page 1 of Tables 1, 2, and 3, ~~in Table I, Columns 1 and 2, of~~ Appendix B to 10 CFR Part 20.~~.~~

(10~~9~~) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(11~~0~~) "Atmosphere supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(12~~1~~) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from radioactive or special nuclear materials regulated by the Department.

(13~~12~~) "Bioassay" (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

(14) “Byproduct m~~M~~aterial” means:

(a~~1~~) Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material.

(b~~2~~) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ‘‘byproduct material’’ within this definition.

(c~~3~~) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity. Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity.

(d~~4~~) Any discrete source of naturally occurring radioactive material, ~~other than source material~~ other than source materials, that:

(A~~a~~)~~.~~ The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate f~~F~~ederal agency determines a threat to the public health and safety or the common defense, is similar to the threat posed by a discrete source of radium-226 material to the public health and safety or the common defense and security; and

(B~~b~~) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical or research activity.

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(15~~13~~) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days; for Class W, Weeks, from 10 to 100 days; and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

(16~~14~~) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(17~~15~~) "Committed dose equivalent" (HT,50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(18~~16~~) "Committed effective dose equivalent" (HE,50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues (HE,50) = The Sum of WTHT,50.

(19~~17~~) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

(20) "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radiopharmaceutical drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a f~~F~~ederal facility or a medical facility.

(21~~18~~) Constraint (dose constraint) means a value above which specified licensee actions are required.

(22~~19~~) "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(23~~20~~) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(24~~21~~) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(a) Release of the property for unrestricted use and termination of the license; or

(b) Release of the property under restricted conditions and termination of the license.

(25~~22~~) "Deep-dose equivalent" (Hd), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm2).

(26~~23~~) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(27~~24~~) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of

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air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of 10 CFR 20 Appendix B.

(28~~25~~) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(29) “Discrete Source” means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

(30~~26~~) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(31~~27~~) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

(32~~28~~) "Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in this rule.

(33~~29~~) "Dose equivalent" (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

(34~~30~~) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(35~~31~~) "Effective Dose Equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factor (WT) applicable to each of the body organs or tissues that are irradiated (HE = The Sum of WTHT).

(36~~32~~) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(37~~33~~) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(38~~34~~) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(39~~35~~) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(40~~36~~) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(41~~37~~) "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2). (See "lens dose equivalent").

(42~~38~~) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of

the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(4339) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(4440) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(4541) "Generally applicable environmental radiation standards" means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(4642) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(4743) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of one mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

(4844) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(4945) "Individual" means any human being.

(5046) "Individual monitoring" means:

(a) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e. DAC-hours; or

(c) The assessment of dose equivalent by the use of survey data.

(5147) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

(5248) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(5349) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm 2).

(5450) "Loose fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(5551) "Member of the public" means any individual except when that individual is receiving an occupational dose.

(5652) "Minor" means an individual less than 18 years of age.

(5753) "Monitoring (radiation monitoring, radiation protection monitoring)" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

(5854) “Nationally Tracked Source” means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of radioactive material listed in 10 CFR Part 20, Appendix E. . In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and that is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel rod, or fuel pellet.
(a) Category 1 nationally traced sources are those containing radioactive material at a quantity equal to or greater than Category 1 threshold.
(b) Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(5955) "Negative pressure respirator (tight fitting)" means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(6056) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "deterministic effect" is an equivalent term.

(6157) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, from voluntary participation in medical research programs, or as a member of the public.

(62) “Particle a~~A~~ccelerator” means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, “accelerator” is an equivalent term.

(6358) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(6459) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(6560) “Powered air purifying respirator” (PAPR) means an air purifying respirator that uses a blower to force the ambient air through air purifying elements to the inlet covering.

(6661) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(6762) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material for medical purposes and released under OAR 333-116-0260, or from voluntary participation in medical research programs.

(6863) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.
(6964) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.
(7065) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.
(7166) "Radiation" (ionizing radiation) means alpha particles, beta particles, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.
(7267) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
(7368) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."
(7469) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site.
(7570) "Restricted area" means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.
(7671) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
(7772) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.
(7873) "Self-contained breathing apparatus" (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.
(7974) "Shallow-dose equivalent" (HS), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of one square centimeter.
(8075) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(8176) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

(8277) "Supplied-air respirator" (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(8378) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

(8479) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(8580) "Total Effective Dose Equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(8681) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

(8782) "User seal check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(8883) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of five gray (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

(89) "Waste" means those low-level radioactive wastes containing source, special nuclear or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined in subsections (14)(b2), (14)(c3), and (14)(d4) ~~of the definition of (14) Byproduct material~~ of this rule.

(9084) "Weighting factor" (WT) for an organ or tissue means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of WT are:

Organ Dose Weighting Factors

Organ or Tissue	WT
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03

Bone surfaces -- 0.03
Remainder -- 0.30 (see (a) below)
Whole Body -- 1.00 (see (b) below)
(a) 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye that receives the highest doses.
(b) For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, WT = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.
(9185) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
(9286) "Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3x105 MeV of potential alpha particle energy.
(9387) "Working level month" (WLM) means an exposure to one working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Waste Disposal

333-120-0500
General Requirements
(1) A licensee must dispose of licensed radioactive material only:
(a) By transfer to an authorized recipient as provided in OAR 333-102-0330; or
(b) By decay in storage; or
(c) By release in effluents within the limits in OAR 333-120-0520; or
(d) As authorized under OAR 333-120-0520, 333-120-0530, and 333-120-0540 and 333-120-0545.
(2) A person must be specifically licensed to receive waste containing licensed material from other persons for:
(a) Treatment prior to disposal; or
(b) Treatment or disposal by incineration; or
(c) Decay in storage; or
(d) Disposal at a land disposal facility licensed under 10 CFR, Part 61 (U.S. Nuclear Regulatory Commission) or equivalent Agreement State regulations; or
(e) Storage until transferred to a storage or disposal facility authorized to receive the waste.
(3) As authorized under the provisions of Oregon Revised Statutes.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-120-0545
Disposal of Certain Byproduct Material

(1) Licensed material as defined in subsections (c~~3~~) and (d~~4~~) of the definition of byproduct material outlined in OAR 333-120-0015(14) may be disposed of in accordance with 10 CFR Part 61 even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61 of this chapter must meet the requirements of OAR 333-120-0550.
(2) A licensee may dispose of byproduct material as defined in sections (c~~3~~) and (d~~4~~) of the definition of byproduct material outlined in OAR 333-120-0015(14) at a disposal facility authorized in accordance with any f~~F~~ederal or s~~S~~tate solid or hazardous waste laws including the Solid Waste Disposal Act as authorized under the Energy Policy Act of 2005.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-120-0550
Transfer for Disposal and Manifests
(1) The requirements of this rule and 10 CFR Part 20 Appendix G to 20.1001 to 20.2401 are designed to control transfers of low-level radioactive waste intended for disposal at a land disposal facility (as defined in 10 CFR Part 61), establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.
(2) Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest as specified in 10 CFR Part 20 section I of Appendix G to 20.1001 to 20.2401.
(3) Each shipment manifest must include a certification by the waste generator as specified in 10 CFR Part 20 section II of **Appendix G** to 20.1001 to 20.2401.
(4) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, must comply with the requirements specified in 10 CFR Part 20 section III of **Appendix G** to 20.1001 to 20.2401.
(5) Any licensee shipping byproduct material defined in subsections (c~~3~~) and (d~~4~~) of the definition of b~~B~~yproduct material outlined in OAR 333-120-0015(14) intended for ultimate disposal at a land disposal facility licensed under 10 CFR Part 61 must document the information required on the Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.
[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807