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

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

Exemptions -- Radioactive Material Other than Source Material

333-102-0010
Exempt Concentrations
(1) Except as provided in sections (3) or (4) of this rule, any person is exempt from this division to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in 10 CFR Part 30.70 Schedule A.
(2) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.
(3) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license to the extent that he transfers radioactive material contained in a product or material in concentrations not in excess of those specified in 10 CFR Part 30.70 Schedule A and introduced into the product or material by a licensee holding a specific license issued by an ~~a~~Agreement State, or the Nuclear Regulatory Commission, expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.
(4) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under section (1) of this rule or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State, or Licensing State except in accordance with a specific license issued pursuant to OAR 333-102-0245 or the general license granted by OAR 333-102-0340.
NOTE: 10 CFR Part 30.70 Schedule A is available from the Agency.
Health Services, Radiation Protection Services.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

Exempt Items

333-102-0103
General Licenses -- Depleted Uranium in Industrial Products and Devices
(1) A general license is hereby granted to receive, acquire, possess, use or transfer, in accordance with the provisions of sections (2), (3), (4) and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
(2) The general license in section (1) of this rule applies only to industrial products or devices that have been manufactured either in accordance with a specific license issued to

the manufacturer of the products or devices pursuant to OAR 333-102-0235 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State that authorizes manufacture of the products or devices for distribution to persons granted a general license by the U.S. Nuclear Regulatory Commission or an Agreement State.
(3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by section (1) of this rule must apply for registration of the general license pursuant to OAR 333-101-0007, and submit the required fee pursuant to 333-103-0015. Applicants will receive a validation certificate from the Agency Application for registration must be submitted within 30 days after the first receipt or acquisition of such depleted uranium.
(a) The general licensee must provide the following information in accordance with the registration application required by OAR 333-101-0007 and such other information as may be required by that form:
(A) Name and address of the general licensee;
(B) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in section (1) of this rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
(C) Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in subsection (3)(b) of this rule.
(b) The general licensee possessing or using depleted uranium under the general license established by section (1) of this rule must report any changes in information in writing to the Agency within 30 days after the effective date of such change.
(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by section (1) of this rule:
(a) Must not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
(b) Must not abandon such depleted uranium;
(c) Must transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of OAR 333-102-0330. In the case where the transferee receives the depleted uranium pursuant to the general license granted by section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by OAR 333-101-0007. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to section (1) of this rule, the transferor must furnish the transferee a copy of this rule and a copy of the general license registration application required by OAR 333-101-0007 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this rule;
(d) Must report in writing to the Agency, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) Must not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
(5) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to the depleted uranium covered by that general license.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

General Licenses -- Radioactive Material Other than Source Material

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 Agency pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.
(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(h) of this rule.
NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.
(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:
(a) Must assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and must comply with all instructions and precautions provided by such labels;
(b) Must assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:
(A) Devices containing only krypton need not be tested for leakage of radioactive material; and
(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting

material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.
(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:
(A) In accordance with the instructions provided by the labels; or
(B) By a person holding an applicable specific license from the Agency, 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 Agency, 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 Agency. 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 Agency within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Agency, on a case-by-case basis;
(f) Must not abandon the device containing radioactive material;
(g) Except as provided in subsection (4)(h) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(k) of this rule, by transfer to another general licensee as authorized in subsection (4)(h) of this rule, or by transfer to a specific licensee of the Agency, 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 Agency, 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 Agency approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.
(h) 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 Agency 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 Agency 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.
(i) 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 these rules;
(j) Must submit the required Agency form and receive from the Agency 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.
(k) 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 Agency any changes in information furnished by the licensee on the required Agency 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 Agency. Devices containing more than 37 MBq (1 mCi) of cesium-

137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), are required to have a specific license. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee.
(b) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Agency:
(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 ~~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 Agency 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 Agency 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 Agency 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 Agency 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 Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in section 32.57 of 10 CFR Part 32, or section 70.39 of 10 CFR Part 70.
(5) The general licenses provided in sections (1), (2) and (3) of this rule are subject to the provisions of OAR 333-100-0005 (Definitions), 333-100-0025 (Exemptions), 333-100-0030 (Additional Requirements), 333-100-0055 (Records), 333-100-0060(1) and 333-100-0060(2) (Inspections), 333-100-0065 (Tests), 333-102-0305(1) through 333-102-0305(8) (Terms and Conditions of Licenses), 333-102-0330 (Transfers), 333-102-0335 (Modification, Revocation, and Termination of Licenses), and divisions 111, and 120 of this chapter. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:
(a) Must not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) each of americium-241, of plutonium-238, plutonium-239, or of radium-226 in such sources; and
(b) Must not receive, possess, use or transfer such source unless the source or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement that contains the information called for in one of the following statements, as appropriate:
(A) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. _____ Name of manufacturer or importer
NOTE: Show only the name of the appropriate material.

(B) The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.
CAUTION - RADIOACTIVE MATERIAL -THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE._____
Name of manufacturer or importer
(c) Must not transfer, abandon or dispose of such source except by transfer to a person authorized by a specific license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;
(d) Must store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 that might otherwise escape during storage; and
(e) Must not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.
[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0130
General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing
(1) A general license is hereby granted to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with sections (2), (3), (4), (5) and (6) of this rule, the following radioactive materials in prepackaged units for use in in Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
(a) Iodine-125 in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;
(b) Iodine-131, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;
(c) Carbon-14, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;
(d) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;
(e) Iron-59 in units not exceeding 20 microcuries (740 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals;

(f) Selenium-75, in units not exceeding ten microcuries (370 kBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals;
(g) Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcuries (185 Bq) of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
(2) A person may not receive, acquire, possess, use or transfer radioactive material under the general license granted by section (1) of this rule unless that person:
(a) Has filed the required Agency application for registration pursuant to OAR 333-101-0007 and submitted the registration fee pursuant to OAR 333-103-0015 and received from the Agency a validated license with certification number assigned; or
(b) Has a license that authorizes the medical use of radioactive material that was issued under OAR 333-116.
(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by section (1) of this rule must comply with the following:
(a) The general licensee must not possess at any one time, at any one location of storage or use a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 200 microcuries (7.4 MBq);
(b) The general licensee must store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
(c) The general licensee must use the radioactive material only for the uses authorized by section (1) of this rule;
(d) The general licensee must dispose of the mock iodine-125 reference or calibration sources described in subsection (1)(g) of this rule as required by OAR 333-120-0500 and section (6);
(e) The general licensee must not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
(4) The general licensee must not receive, acquire, possess or use radioactive material pursuant to section (1) of this rule:
(a) Except as prepackaged units that are labeled in accordance with the provisions of an applicable specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59 or mock iodine-125 for distribution to persons generally licensed under section (1) of this rule or its equivalent; and
(b) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
(A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or

laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

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

_____
Name of Manufacturer

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

(6) Any person using radioactive material pursuant to the general license granted by section (1) of this rule is exempt from the requirements of divisions 111 and 120 of this chapter with respect to radioactive material covered by that general license, except that such persons using mock iodine-125 described in subsection (1)(g) of this rule must comply with provisions of OAR 333-120-0500, 333-120-0700 and 333-120-0710.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0190

Application for Specific Licenses.

(1) Applications for specific licenses must be filed on a form prescribed by the Agency. Information contained in previous applications, statements or reports filed with the Agency, 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 Agency 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 Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

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

(5) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in OAR 333-103-0010.
(6) An application for a license to receive and possess radioactive material for the conduct of any activity that the Agency has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect the quality of the environment, must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.
(7) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:
(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or
(b) Contain the information identified in 10 CFR Part 32.210(c).
(8) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:
NOTE: If a renewal application was submitted on or before July 27, 1990, the decommissioning information may follow the renewal application but must be submitted prior to the license being issued.
(9)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:
(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or
(B) An emergency plan for responding to a release of radioactive material.
(b) One or more of the following factors may be used to support an evaluation submitted under ~~section~~paragraph (9)(a)(A) of this rule:
(A) The radioactive material is physically separated so that only a portion could be involved in an accident;
(B) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
(C) The release fraction in the respirable size range would be lower than the release fraction shown in 10 CFR Part 30.72 (Schedule C -- Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) due to the chemical or physical form of the material;
(D) The solubility of the radioactive material would reduce the dose received;
(E) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR Part 30.72;

(F) Operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR Part 30.72; or
(G) Other factors appropriate for the specific facility.
(c) An emergency plan for responding to a release of radioactive material submitted under ~~section~~paragraph (9)(a)(B) of this rule must include the following information:
(A) Facility description. A brief description of the licensee's facility and area near the site.
(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.
(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.
(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.
(G) Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Agency; 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 Agency 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 Agency.
(J) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.
(M) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.
(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to Agency. The licensee must provide any comments received within the 60 days to the Agency 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

333-102-0203
Definitions
The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:
NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.
(1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe, etc. samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.
(2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.
(3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by OAR 333-103-0010(2)(m)), or

other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.
(4) "Beneficiating" means subjecting a product to any process that will increase or concentrate any component (including the radioactive materials) to benefit the product~~;~~.
(5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with 333-116-0420. Brachytherapy includes radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.
(6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.
(7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.
(8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.
(9) "Commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site.
(10) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.
(11) "Decontamination and Decommissioning" means:
(a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and
(b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.
(12) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.
(13) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.
(14) "Exempt Source" means radioactive material, exempt from the rules in this chapter.
(15) "Facility" means location of licensed activities under the direct control of licensee management. If a "Facility," as used in this division, includes multiple separate addresses, the Agency may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.
(16) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-Ray & Hybrid Gauges pursuant to division 115 of this chapter, that contain either an x-ray source or a radioactive sealed source.

(17) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.
(18) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0103.
(19) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.
(20) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.
(21) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.
(22) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.
(23) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.
(24) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed; conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.
(25) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.
(26) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.
(27) "Generators and Kits" means "Imaging and Localization."
(28) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.
(29) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.
(30) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an x-ray source, pursuant to division 115 of this chapter.

(31) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by OAR 333-102-0130(2).
(32) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-0800 through 333-116-0880.
(33) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.
(34) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.
(35) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.
(36) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.
(37) "Irradiator Self-shielded or Other -- Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.
(38) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.
(39) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.
(40) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.
(41) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.
(42) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (13) and (41) of this rule and require separate specific licenses for each activity.
(43) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.

(44) “Nationally Tracked Source” means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR part 32 Appendix E.
(~~44~~45) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05% source material.
(~~45~~46) "Net working capital" means current assets minus current liabilities.
(~~46~~47) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.
(~~47~~48) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.
(~~48~~49) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.
(~~49~~50) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(n) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.
NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR 345-050. Any material that contains NORM requires a specific license unless exempted in OAR 345-050. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.
(~~50~~51) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).
(~~51~~52) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.
NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license should specify which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.
(~~52~~53) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices

that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.
NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).
(~~53~~54) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.
(~~54~~55) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.
NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).
(~~55~~56) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by 333-116-0800 and included in the facility specific license issued pursuant to OAR 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.
(~~56~~57) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.
(~~57~~58) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.
(~~58~~59) "Principal Activities" means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
(~~59~~60) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (e.g., breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").
(~~60~~61) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).
(~~61~~62) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.
(~~62~~63) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to OAR 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.

(6364) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with OAR 333-116-0360.
(6465) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.
(6566) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in OAR 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to OAR 333-103-0010 and 333-103-0015.
(6667) "Responsible Representative" means
(a) The person designated as having responsibility for general license device or general license material;
(b) The person management has selected to certify general license inventory; and
(c) The individual responsible to the Agency and to management to ensure that all regulatory elements are adequate.
(6768) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.
NOTE: The Agency no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.
(6869) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.
(6970) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with OAR 333-116-0400.
(7071) "Special Nuclear Material" means:
(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or
(b) Any material artificially enriched by any of the foregoing but does not include source material.
(7172) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be ~~annoted~~ annotated on the specific license, and validated with a specific license fee pursuant to 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").
(7273) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

(~~73~~74) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets would not include intangibles such as goodwill and rights to patents or royalties.
(~~74~~75) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."
(~~75~~76) "Temporary Job Site" means any location, where specific license material is used that is either:
(a) Not the specific location of the licensee if an in-state licensee; or
(b) Any location in the State if an out-of-state specific licensee pursuant to a specific radioactive materials license.
NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.
(~~76~~77) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.
(~~77~~78) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to Agencies in the Department of Human Services.
(~~78~~79) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in 333-116-0300 for uptake, dilution, and excretion studies.
(~~79~~80) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.
NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.
(~~80~~81) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to OAR 333-116-0280;
(~~81~~82) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.
(~~82~~83) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.
NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0235

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

(1) An application for a specific license to manufacture, or initially transfer devices containing radioactive material, excluding special nuclear material, to persons granted a general license by OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

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

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

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

(B) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device; and it is unlikely that any person will receive in one year a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100; and

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

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

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

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

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

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

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

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

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

CAUTION - RADIOACTIVE MATERIAL

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(Name of manufacturer or initial transferor)
NOTE: Devices licensed under 10 CFR Part 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1,1975. The model, serial number, and name of manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.
(D) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in 333-120-0400, and the name of the manufacturer or initial distributor.
(E) Each device meeting the criteria of 333-102-0115(9)(a), bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in 333-120-0400.
(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or both, the applicant must include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information that includes, but is not limited to:
(a) Primary containment (source capsule);
(b) Protection of primary containment;
(c) Method of sealing containment;
(d) Containment construction materials;
(e) Form of contained radioactive material;
(f) Maximum temperature withstood during prototype tests;
(g) Maximum pressure withstood during prototype tests;
(h) Maximum quantity of contained radioactive material;
(i) Radiotoxicity of contained radioactive material; and
(j) Operating experience with identical devices or similarly designed and constructed devices.
(3) In the event the applicant desires that the general licensee under OAR 333-102-0115, or under equivalent rules of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, be authorized to install the device, collect the sample to be ~~analysed~~analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant must include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general

license, is unlikely to cause that individual to receive a dose in excess of ten percent of the annual limits specified in OAR 333-120-0100.
(4) Prior to transfer of a device to a person granted a general license by OAR 333-102-0115(1), the licensee must:
(a) Furnish a copy of the general license contained in OAR 333-102-0115 to each person to whom the licensee directly, or through an intermediate person, transfers radioactive material in a device for use pursuant to the general license contained in OAR 333-102-0115;
(b) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State's rules equivalent to OAR 333-102-0115. Alternatively, a copy of the general license contained in OAR 333-102-0115 must be furnished to each person to whom directly, or through an intermediate person, is transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State or the Licensing State. If a copy of the general license in OAR 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State under requirements substantially the same as those in OAR 333-102-0115;
(c) Report to the Agency all transfers of such devices to persons for use under the general license in OAR 333-102-0115. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons granted a general license by OAR 333-102-0115 during the reporting period, the report must so indicate. The report must cover each calendar quarter and must be filed within 30 days after the end of each quarter;
(d) Furnish reports to other agencies
(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 31.5 of 10 CFR Part 31. Reports must be submitted on the NRC form "Transfers of Industrial Devices Report" or on a clear and legible report containing all of the data required by the form. The required information includes:
(i) The identity of each general licensee by name and address;
(ii) The name and phone number of the person designated by the general licensee to be responsible for ensuring compliance with the appropriate regulations and requirements;
(iii) The date of transfer;
(vi) The type, model number, and serial number of the device transferred; and
(v) The quantity and type of byproduct material contained in the device.
(B) If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include the same information for each intermediate person, and clearly designate that person as an intermediate person.

(C) If the device transferred replaced another returned by the general licensee, report also the type, model number, and serial number of the one returned.
(D) If no transfers have been made to persons generally licensed under 10 CFR 31.5 or OAR 333-102-0115 during the reporting period, the report must so indicate.
(E) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
(F) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
(e) Report to the responsible Agreement or Licensing State Agency all transfers of such devices to persons for use under a general license in an Agreement State's regulations equivalent to OAR 333-102-0115. Such reports must identify all of the information in 333-102-0235(4)(d) of this rule, including each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report must include identification of each intermediate person by name, address, contact and relationship to the intended user. The report must be submitted within 30 days after the end of each calendar quarter in which such device is transferred to the person granted a general license;
(f) If no transfers have been made to U.S. Nuclear Regulatory Commission's licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission;
(g) If no transfers have been made to persons granted a general license within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Agency;
(h) Keep records showing the name, address and the point of contact for each general licensee to whom directly, or through an intermediate person is transferred radioactive material in devices for use pursuant to the general license provided in OAR 333-102-0115 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records should show the date of each transfer, the isotope and the quantity of radioactive material in each device transferred, the identity of any intermediate person and compliance with the reporting requirements of section (4)(h) of this rule. Records required by this rule must be maintained for a period of three years following the estimated useful life of the device or the date of final disposition, if known;
(i) Furnish a list of the services that only can be performed by a specific licensee, and information on acceptable disposal options, including estimated costs of disposal, to each person to whom he directly, or through an intermediate person, transfers radioactive material in a device for use under the general license granted in 333-102-0115;
(j) Furnish the name, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained. If a copy of the general license in OAR 333-102-0115 is furnished to such person, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State.

(k) Label each device transferred if more than one year after the effective date of this rule in accordance with the labeling requirements in 10 CFR Part 32.51(a)(3) through (5).
(l) If a notification of bankruptcy has been made under 10 CFR Part 30.34(h) or the license is to be terminated, provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under 10 CFR Part 32.52(c).
(5) License Conditions.
(a) If a device containing radioactive material is to be transferred for use under the general license contained in 333-102-0115, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
(A) A copy of the general license contained in 333-102-0115; if 333-102-0115(4)(b) through (d) or 333-102-0115(8) do not apply to the particular device, those sections may be omitted;
(B) A copy of 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710;
(C) A list of the services that can only be performed by a specific licensee;
(D) Information on acceptable disposal options including estimated costs of disposal; and
(b) If radioactive material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under this rule must provide the information specified in this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:
(A) A copy of the Agreement State's regulations equivalent to 333-102-0115, 333-100-0055, 333-100-0057, 333-120-0700 and 333-120-0710 or a copy of 10 CFR Secs. 31.5, 31.2, 30.51, 20.2201, and 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it must be accompanied by a note explaining that use of the device is regulated by the Agreement State. If certain sections of the regulations do not apply to the particular device, those sections may be omitted;
(B) A list of the services that can only be performed by a specific licensee;
(C) Information on acceptable disposal options including estimated costs of disposal; and
(D) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or the Nuclear Regulatory Commission from which additional information may be obtained.
[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

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

333-102-0245

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

An application for a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the radioactive material: will be approved if the applicant:

(1) Satisfies the general requirements specified in OAR 333-102-0200;

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

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

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

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

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0247

Records and Material Transfer Reports

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

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

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

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

(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
(C) The date of transfer;
(D) The type, model number, and serial number of the device transferred; and
(E) The quantity and type of byproduct material contained in the device.
(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
(c) For devices received from a 333-102-0115 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
(d) If the licensee makes changes to a device possessed by a 333-102-0115 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
(f) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
(g) If no transfers have been made to or from persons generally licensed under 333-102-0115 during the reporting period, the report must so indicate.
(2) The licensee must report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to 333-102-0115 and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State Agency.
(a) The required information for transfers to general licensees includes:
(A) The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, an alternate address for the general licensee must be submitted along with information on the actual location of use.
(B) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;
(C) The date of transfer;
(D) The type, model number, and serial number of the device transferred; and
(E) The quantity and type of byproduct material contained in the device.
(b) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).
(c) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of

the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
(d) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.
(e) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.
(f) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.
(g) If no transfers have been made to or from a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon request of the Agency.
(3) The licensee must maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this section must be maintained in accordance with 333-100-0057.
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.
(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 ~~sections~~paragraphs (1)(b)(C) or (D) of this rule:
(a) May prepare radioactive drugs for medical use, as defined in OAR 333-116-0020, provided that the radioactive drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(c) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.
(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:
(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;
(B) This individual meets the requirements specified in OAR 333-116-0910 and 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or
(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(c) of this rule.
(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.
(d) May designate a pharmacist (as defined in OAR 333-116-0020 as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the Agency pursuant to this division.
(e) Must provide to the Agency 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 ~~sections~~paragraphs (2)(b)(A) and (C) of this rule, the individual to work as an authorized nuclear pharmacist.
(3) A licensee must possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee must have procedures for use of the instrumentation. The licensee must measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee must:
(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument and make adjustments when necessary; and
(b) Check each instrument for constancy and proper operation at the beginning of each day of use.
(4) Nothing in this rule relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.
NOTE: Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the Agency 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

333-102-0293
Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications
(1) An application for a specific license to manufacture industrial products or devices containing depleted uranium for use pursuant to OAR 333-102-0103 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:
(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;
(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses and potential hazards of the industrial product or device to provide reasonable assurance that possession, use or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in OAR 333-120-0100; and
(c) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under this rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
(3) The Agency may deny any application for a specific license under this rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.
(4) Each person licensed pursuant to section (1) of this rule must:
(a) Maintain the level of quality control required by the license in the manufacture of the industrial product or device; and in the installation of the depleted uranium into the product or device;
(b) Label or mark each unit to:
(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium and the quantity of depleted uranium in each product or device; and
(B) State that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: Depleted Uranium.
(A) Furnish a copy of the general license contained in OAR 333-102-0103 to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in OAR 333-102-0103; or
(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to OAR 333-102-0103 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in OAR 333-102-0103 to each person to whom depleted uranium in a product or device is ~~transfered~~transferred for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in OAR 333-102-0103.
(d) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in OAR 333-102-0103. Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons granted a general license by OAR 333-102-0103 during the reporting period, the report must so indicate.
(e) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in section 40.25 of 10 CFR Part 40.
(A) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to OAR 333-102-0115 for use under a general license in that state's regulations equivalent to OAR 333-102-0103.
(B) Such report must identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred and the quantity of depleted uranium contained in the product or device. The report must be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.
(C) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information must be reported to the U.S. Nuclear Regulatory Commission.
(f) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State Agency upon the request of that Agency.
(g) Keep records showing the name, address and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in OAR 333-102-0101(4) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The

records must be maintained until inspection by the Agency and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of section (9) of this rule.
(h) Licensees required to submit emergency plans by OAR 333-102-0190(9) must follow the emergency plan approved by the Commission. The licensee may change the plan without Commission approval if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Agency.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0310
Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.
(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.
(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:
(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(9);
(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:
(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or
(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;
(C) Specific licenses whose holders are listed in the SDMP List published in NUREG 1444, Supplement 1 (November 1995);
(D) Specific licenses who need an environmental assessment or environmental impact statement pursuant to Subpart A of Part 51 and OAR 333-102-0200(5);
(E) Specific licenses whose holders have not had at least one Agency inspection of licensed activities before February 15, 1996;

(F) Specific licenses whose holders, as the result of the most recent Agency inspection of licensed activities conducted before February 15, 1996, have been:
(i) Cited for a serious health and safety noncompliance;
(ii) Subject to an Order issued by the Agency; or
(iii) Subject to a Confirmatory Action Letter issued by the Agency.
(G) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.
(2) Each specific license revoked by the Agency expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.
(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee must:
(a) Limit actions involving material to those related to decommissioning; and
(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.
(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by section (7)(a) of this rule, and begin decommissioning upon approval of that plan if:
(a) The license has expired pursuant to sections (1) or (2) of this rule; or
(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or
(c) No principal activities under the license have been conducted for a period of 24 months; or
(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.
(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to section (7)(d)(E) of this rule.
(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.
(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Agency.

(6) The Agency may grant a request to extend the time periods established in section (4) of this rule if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Agency has made a determination on the request.
(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:
(A) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
(B) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or
(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.
(b) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.
(c) Procedures such as those listed in section (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.
(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:
(A) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
(B) A description of planned decommissioning activities;
(C) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
(D) A description of the planned final radiation survey; and
(E) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
(F) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.
(e) The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.
(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.
(9) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:
(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;
(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;
(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
(e) Other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.
(10) As the final step in decommissioning, the licensee must:
(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and
(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:
(A) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters -- removable and fixed -- for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and
(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.
(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:
(a) Radioactive material or source material has been properly disposed;
(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or
(B) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.
(d) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:
(A) The licensee must retain each record of receipt of radioactive material or source material as long as the material is possessed and for three years following transfer or disposal of the material.
(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.
(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Agency terminates each license that authorizes disposal of the material.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0330
Transfer of Material
(1) No licensee may transfer radioactive material except as authorized pursuant to this rule.
(2) Except as otherwise provided in the license and subject to the provisions of sections (3) and (4) of this rule, any licensee may transfer radioactive material:
(a) To the Agency;
NOTE: A licensee may transfer radioactive material to the Agency only after receiving prior approval in writing from the Agency.
(b) To the U.S. Department of Energy;
(c) To any person exempt from the rules in this division to the extent permitted under such exemption;
(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State or a Licensing State; or
(e) As otherwise authorized by the Agency in writing.
(3) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material must verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

(4) Any of the following methods for the verification required by section (3) of this rule are acceptable:
(a) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;
(b) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;
(c) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;
(d) The transferor may obtain other information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration;
(e) When none of the methods of verification described in subsections (4)(a) through (4)(d) of this rule are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.
(5) Shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0335
Modification, Revocation and Termination of Licenses
(1) The terms and conditions of each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be subject to amendment, revision or modification or by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act by the Agency.
(2) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means that would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or of any rule, regulation or order of the US Nuclear Regulatory Commission or the Agency.
(3) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings ~~therefor~~therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee

shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
(4) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.
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 Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 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 Agency using the Agency Reciprocity Application form at least three days prior to engaging in such activity and has paid the applicable registration fee pursuant to OAR 333-103-0030. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency 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 Agency 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 Agency or laws of the State of Oregon;
(d) The out-of-state licensee supplies such other information as the Agency 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 Agency 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 Agency 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 Agency having jurisdiction over the manufacture and distribution of the device.
(3) The Agency may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.
(4) The out-of-state licensee shall at all times during work at any work location within the state have available the pertinent licensing document, the applicable sections of the State of Oregon radiation regulations, a complete source inventory, pertinent U.S. Department of Transportation documentation, leak test records, instrument calibration records, personnel training records, and necessary documentation required by applicable special requirements of these regulations.
(5) While working in Oregon, the out-of-state licensee shall notify the Agency (in writing, indicating date and court) immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (bankruptcy) of the United States code by or against:
(a) The licensee;
(b) An entity (as that term is defined in II U.S.C 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or
(c) An affiliate (as that term is defined in II U.S.C. 101(2)) of the license.
(6) The out-of-state licensee shall notify the Agency within one hour after arrival at the actual work location within the state and notification within one hour after any change of work location within the state.
(7) If multiple work crews or persons work concurrently at more than one work location under a general license granted pursuant to this rule, each day worked at each location shall count toward the limit of 180 days in a calendar year.
(8) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U. S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or any product distributed pursuant to such

licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.
(9) Each general licensee granted authorization to conduct activities within the State of Oregon pursuant to this rule, based upon an acceptable licensing document, will receive acknowledgment from the Agency. This acknowledgment shall be kept at the site of use.
(10) Each general licensee granted authorization to conduct activities within the state of Oregon pursuant to this rule based upon an acceptable licensing document is subject to the reciprocity fee and may be inspected by the Agency. The fee for the general license granting reciprocity shall:
(a) Be charged as provided by division 103 of this chapter; and
(b) Shall not be charged more often than once during each calendar year.
(11) Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0345
Special Procedures in Regulatory Review
(1) The provisions of ORS 183 governing contested cases are applicable in any case where the Agency proposes to refuse to issue, renew, modify, amend, revise, revoke or suspend a general or specific license or to find noncompliance with or to refuse to grant exemption from a regulation of the Agency.
(2) In any case where the Agency proposes to grant, issue, renew, modify, amend or revise a general or specific license, or to find compliance or to grant exemption from a regulation of the Agency and the Assistant Director of the Public Health Division ~~Administrator~~ determines that such action would first merit public notice and opportunity for hearing, the following procedures shall be applicable:
(a) Notice of the proposed action shall be published in the Secretary of State's bulletin or a newspaper of general circulation in the state, which notice shall provide that within 15 days of the day of publication of the notice, any person whose interest may be affected by the outcome of the proceeding, or who represents a public interest in the results of the proceeding, may file a petition to be made a party and given an opportunity for hearing in the matter. The notice of proposed action shall set forth:
(A) The nature of the action proposed;
(B) The manner in which and the location at which inspection may be made of the Agency records pertaining to the proposed action; and
(C) A reference of the Agency's rules governing institution and conduct of hearings in radiation control proceedings.
(b) If no request for hearing is filed within the time prescribed in the notice, the proposed action shall be taken;
(c) If a hearing is requested, the person requesting to participate as a party must file a petition requesting party status and opportunity for hearing, setting forth the same information required of a person requesting party status in a contested case when the Agency has given notice that it intends to hold a contested case hearing pursuant to OAR

137-003-0005(6). The same procedures for determining party status under OAR 137-003-0005 shall be followed upon receipt of the petition;
(d) If the Agency allows party status, it shall in the same order set the time for a contested case hearing and provide notice of the order to the petitioner and all parties;
(e) A contested case shall proceed in accordance with the provisions of ORS 183 governing contested cases.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

333-102-0355
Records
(1) Each person who receives radioactive material pursuant to a license issued in accordance with the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must keep records showing the receipt, transfer, and disposal of the radioactive material as follows:
(a) The licensee must retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.
(b) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another division of the rules in this chapter dictates otherwise.
(c) The licensee who disposed of the material must retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.
(2) The licensee must retain each record that is required by the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.
(3)(a) Records that must be maintained pursuant to this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Agency rules. The record also may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, or specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with and loss of records.
(b) If there is a conflict between the Agency's rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter, license condition, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter for such records must apply unless the Agency, pursuant to OAR 333-102-0003, has granted a specific exemption from the record retention requirements specified in the rules in this division or divisions 105, 113, 115, 116, 117, and 121 of this chapter.

(4) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, must forward the following records to the Agency office:
(a) Records of disposals of licensed material made prior to January 28, 1981; and
(b) Records required by OAR 333-120-0620(2)(d).
NOTE: Prior to Oregon Department of Energy's Energy Facility Siting Council rules for burial of small quantities of licensed materials in soil was permitted without specific Agency authorization.
(5) If licensed activities are transferred or assigned in accordance with OAR 333-102-0305(2), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, must transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:
(a) Records of disposal of licensed material made under OAR 333-120-0510 (including burials authorized before January 28, 1981), 333-120-0520, 333-120-0530, 333-120-0540; and
(b) Records required by OAR 333-120-0620(2)(d).
(6) Prior to license termination, each licensee must forward the records required by OAR 333-102-0200(6) to the Agency office.
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 30.100, Schedule A, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 30.100, Schedule A, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 30.100, Schedule A Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity;
(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of

radioactive material specified in 10 CFR, Part 30.100, Schedule A, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 10 CFR, Part 30.100, Schedule A, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR, Part 30.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license must not exceed unity.
(2) An application for a Type A specific license of broad scope will be approved if:
(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;
(b) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:
(A) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material;
(B) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
(C) The establishment of appropriate administrative procedures to assure:
(i) Control of procurement and use of radioactive material;
(ii) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and
(iii) Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with ~~section~~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 ~~section~~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 Agency 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, 333-105, 333-110, 333-113, 333-115, 333-116, or 333-117 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