Final Rules for RATS 2018-1

For 30.34(g)

333-102-0305
Specific Terms and Conditions of License

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority.

(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(3) An application for transfer of license must include:

(a) The identity, technical and financial qualification of the proposed transferee; and

(b) Financial assurance for decommissioning as required by 10 CFR Parts 30.35, 40.36, 40.46, 70.25, or 70.36.

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

(5) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth by the Authority, whether or not these provisions are expressly set forth in the license.

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

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

(b) Protect restricted data; and

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

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

(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85, respectively, in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed within OAR 333-116-0330 at the time of generator elution, in accordance with OAR 333-116-0330.

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

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

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

(b) This notification must indicate:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(24) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with OAR 333-116-0290.

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

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

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

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

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

(30) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs.

(31) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall:

(a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-102-0285(3).

(32) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be:

(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(33) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of OAR 333-116-0910.

Statutory/Other Authority: ORS 453.635 & 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

For 32.72

333-102-0275

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Licensing the Manufacture and Distribution of Ice Detection Devices

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

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

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

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

Statutory/Other Authority: ORS 453.635 & 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.2
333-116-0020
Definitions

As used in this division, the following definitions apply:

(1) "Address of use" means the building or buildings identified on the license as the location(s) where radioactive material may be received, used, or stored.

(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.

(3) "Associate Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0740 and 333-116-0760; or

(b) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct materials for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(A) A specific medical use license issued by the Authority, U.S. Nuclear Regulatory Commission, or an Agreement State; or

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee.

(4) "Attestation" means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission’s form 313A.

(5) "Authorized Medical Physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0730, or 333-116-0905 and 333-116-0760; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the Authority or an Agreement State or the US Nuclear Regulatory Commission;

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

(6) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in OAR 333-116-0910.

(b) Is identified as an authorized nuclear pharmacist on an Authority, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material in the practice of nuclear pharmacy;

(c) Is identified as an authorized nuclear pharmacist on a license issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or

(d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy licensed (authorized) by the Authority, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.

(7) "Authorized user" means a physician, dentist or podiatrist who:

(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;

(b) Is identified as an authorized user on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

(c) Is identified as an authorized user on a permit issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.

(8) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.

(9) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

(10) "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose of

radiation within a few centimeters, by surface, intracavitary, or interstitial application that is not designed to be disassembled by the user.

(11) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

(12) "Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(13) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(14) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

(15) "High dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate in excess of two gray (200 rad) per hour, to the point or surface where the dose is prescribed.

(16) "Human Research Subject" means a living person that an authorized user, conducting research, obtains data resulting from the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to the individual. For the purpose of these rules, unless otherwise noted, the term patient applies to a human research subject.

(17) "Low dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate of less than two gray (200 rad) per hour, to the point or surface where the dose is prescribed.

(18) "Management" means the chief executive officer or that individual's designee.

(19) "Manual Brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed on, or in close proximity, to the treatment site or inserted directly into the tissue volume.

(20) "Medical Event" means an event that meets the criteria in OAR 333-116-1000.

(21) "Medical institution" means an organization in which more than one medical discipline is practiced.

(22) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(23) "Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

(24) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(25) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 333-116-0910 in the management and handling of radiopharmaceutical drugs and is authorized by license to receive, use, transfer, and dispose of such radiopharmaceutical drugs.

(26) "Ophthalmic physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0447 and OAR 333-116-0760; and

(b) Is identified as an ophthalmic physicist on a:

(A) Specific medical use license issued by the Authority, U.S. or Nuclear Regulatory Commission, or an Agreement State.

(B) Permit issued by an Agreement State, Authority, or U.S. Nuclear Regulatory Commission broad scope medical use licensee.

(C) Medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

(D) Permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

(27) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(28) "Patient Intervention" means actions taken by a patient or human research subject, whether intentional or unintentional, interrupt or terminate the administration of radioactive materials or radiation.

(29) "PET" means Positron Emission Tomography.

(30) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.

(31) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.

(32) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.

(33) "Pharmacist" means an individual licensed by a state or territory of the United States, The District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(34) "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(35) "Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(36) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(37) "Positron Emission Tomography (PET) facility" means a facility comprised of an accelerator that produces positron-emitting isotopes, a radiopharmacy that specializes in preparation of PET radiopharmaceuticals, and/or a clinic that uses PET isotopes for medical diagnostic purposes.

(38) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, Radiation Safety Officer or an Associate Radiation Safety Officer. The preceptor must have previously met all of the applicable requirements and be so named on a radioactive materials license issued by the Authority, the Nuclear Regulatory Commission, an Agreement State or licensing state.

(39) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical or radioisotope as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(40) "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(41) "Pulsed dose-rate remote afterloader" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(42) "Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or

(b) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

(43) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(44) "Stereotactic Radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

(45) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(46) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(47) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on an Authority license.

(48) "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(49) "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

(50) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(51) "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Authority as a nuclear pharmacy.

(52) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

(53) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:

(a) For any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131: the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(f) For all other brachytherapy:

(A) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.13
333-116-0040
License Amendments

A licensee must apply for and must receive a license amendment:

(1) Before receiving or using radioactive material for a method or type of medical use not permitted by the license issued under this division;

(2) Before permitting anyone to work as an authorized user, authorized nuclear pharmacist, ophthalmic physicist, or authorized medical physicist under the license except:

(a) For an authorized user; an individual who meets the requirements in OAR 333-116-0760, 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0710 and 333-116-0720.

(b) For an authorized nuclear pharmacist; an individual who meets the requirements in OAR 333-116-0910 and 333-116-0760.

(c) For an authorized medical physicist; an individual who meets the requirements in OAR 333-116-0905 and 333-116-0760.

(d) An individual identified as an authorized user, authorized nuclear pharmacist, ophthalmic physicist or an authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy.

(3) Before changing the Radiation Safety Officer except as provided in OAR 333-116-0090;

(4) Before permitting anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(5) Before receiving a sealed source from a different manufacturer or of a different model number than authorized by the license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(6) Before receiving radioactive material in excess of the amount authorized on the license;

(7) Before adding to or changing the areas of use or mailing address identified on the license; and

(8) Before revising procedures required by OAR 333-116-0495, 333-116-0580, 333-116-0583, and 333-116-0587 as applicable where such revision reduces radiation safety.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.14
333-116-0050
Notifications

(1) A licensee shall provide the Authority, no later than 30 days after the date that the licensee permits an individual to work under the provisions of OAR 333-116-0040 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:

(a) A copy of the board certification and, as appropriate, verification of completion of:

(A) Training for the authorized medical physicist under OAR 333-116-0905;

(B) Any additional case experience required in OAR 333-116-0680 for an authorized user under OAR 333-116-0360; or

(C) Device specific training in OAR 333-116-0720 for the authorized user under OAR 333-116-0480; or

(b) A copy of the U.S. Nuclear Regulatory Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

(2) A licensee shall notify the Authority no later than 30 days after:

(a) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, Associate Radiation Safety Officer, authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee permits an individual qualified to be a Radiation Safety Officer under OAR 333-116-0740 and OAR 333-116-0760 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with OAR 333-116-0090;

(c) The licensee's mailing address changes;

(d) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in OAR 333-102-0305;

(e) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either OAR 333-116-0300 or 333-116-0320 if the change does not include addition or relocation of either an area where PET

radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

(f) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in OAR 333-116-0040. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(3) The licensee shall send the documents required in this section to the Authority at Radiation Protection Services, 800 N.E. Oregon St., Suite 640, Portland Oregon, 97232.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.15
333-116-0055
Exemptions Regarding Type A Specific Licenses of Broad Scope

A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(1) The provisions of OAR 333-116-0040(2);

(2) The provisions of OAR 333-116-0040(7) regarding additions to or changes in areas of use only at the addresses specified in the license;

(3) The provisions of OAR 333-116-0050(1);

(4) The provisions of OAR 333-116-0050(2)(a) for an authorized user, ophthalmic physicist or authorized nuclear pharmacist, and

(5) The provisions of OAR 333-116-0140(1).

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.24
333-116-0090
Authority and Responsibilities for the Radiation Protection Program

(1) In addition to the radiation protection program requirements of OAR 333-120-0020, a licensee's management must approve in writing:

(a) Requests for a license application, renewal, or amendment before submittal to the Authority;

(b) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(c) Radiation protection program changes that do not require a license amendment and are permitted under OAR 333-116-0123.

(2) A licensee's management must appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer, under OAR 333-116-0650, 333-116-0740 and 333-116-0760, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in section (7) of this rule, if the licensee takes the actions required in sections (2), (5), (7) and (8) of this rule and notifies the Authority in accordance with OAR 333-116-0050(2).

(4) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with section (3) of this rule, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different types of uses of byproduct material permitted by the license.

(5) A licensee must establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(6) A licensee must provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

(a) Identify radiation safety problems;

(b) Initiate, recommend, or provide corrective actions;

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(7) Licensees that are authorized for two or more different types of uses of radioactive material under OAR chapter 333, division 116, must establish a Radiation Safety Committee to oversee

all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

(8) A licensee's Radiation Safety Committee must meet at intervals not to exceed six months. The licensee must maintain minutes of each meeting in accordance with OAR 333-100-0057.

(9) A licensee must retain a record of actions taken under sections (1), (2) and (5) of this rule in accordance with OAR 333-100-0057. These records must be retained for the life of the license.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.40
333-116-0105
Written Directives

(1) A written directive must be prepared, dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (30 microcuries (uCi)), or any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from radioactive material.

(a) If, because of the emergent nature of the patient’s condition, a delay in order to provide a written directive would jeopardize the patient’s health, an oral directive is acceptable.

(b) The information contained in the oral directive must be documented as soon as possible in writing in the patient’s record.

(c) A written directive must be prepared within 48 hours of the oral directive.

(2) The written directive must contain the patient or human research subject's name and the following:

(a) For any administration of quantities greater than 1.11 MBq (30 uCi) of sodium iodide I-131 or I-125; the dosage;

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume for each anatomically distinct treatment site;

(d) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(e) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(f) For permanent implant brachytherapy:

(A) Prior to implantation: treatment site, the radionuclide, number of sources and source strengths or dose; and

(B) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or equivalently, the total dose).

(g) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(A) Before implantation: The treatment site, radionuclide, and the dose; and

(B) After implantation but before completion of the procedure: The radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date.

(3) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(4) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(5) The licensee must retain the written directive in accordance with OAR 333-100-0057.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.41
333-116-0107
Procedures for Administrations Requiring a Written Directive

(1) For any administration requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that:

(a) The patient's or human research subject's identity is verified before each administration; and

(b) Each administration is in accordance with the written directive.

(2) The procedures required by section (1) of this rule must, at a minimum, address the following items applicable to the licensee's use of radioactive material:

(a) Verifying the identity of the patient or human research subject;

(b) Verifying that the specific details of the administration are in accordance with the written directive and, if applicable, the treatment plan;

(c) Checking both manual and computer-generated dose calculations;

(d) Verifying that any computer-generated dose calculations are correctly transferred into the console of therapeutic medical units authorized by OAR 333-116-0480 and 333-116-0485;

(e) Determining if a medical event, as defined in OAR 333-116-0020 has occurred; and

(f) Determining for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(3) The licensee must retain a copy of procedures in accordance with OAR 333-100-0057.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.50
333-116-0640
Radiation Safety Officer and Associate Radiation Safety Officer Training and Experience Requirements

Except as provided in OAR 333-116-0740, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in OAR 333-116-0090 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (4) of this rule.

(a) The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission’s Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(B) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(C) Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have two years of full-time practical training and supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0670, 333-116-0680 or 333-116-0740;

(C) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Has completed a structured educational program consisting of 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an U.S. Nuclear

Regulatory Commission, Authority or Agreement State license, or permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a U.S. Nuclear Regulatory Commission, Authority's or an Agreement State license or permit issued by a U.S. Nuclear Regulatory master material licensee. The full-time radiation safety experience must involve the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of radioactive material.

(h) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in sections (2) and (4) of this rule, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or an Associate Radiation safety Officer, and meets the requirements in section (4) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an Authority, U.S. Nuclear Regulatory Commission, or an Agreement State license, a permit issued by a U.S. Regulatory Commission, Authority licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in section (4) of this rule.

(4) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.51
333-116-0905
Training for Authorized Medical Physicist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section (3) of this rule. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensees Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this rule, by the U.S. Nuclear Regulatory Commission or an Agreement State; or

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740, 333-116-0690 or 333-116-0720; and

(c) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work

experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(a) This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

(C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(D) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (2) and subsection (3)(a) of this rule, and has achieved a level of competency sufficient to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, OAR 333-116-0740, 333-116-0905, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.55
333-116-0910
Training for an Authorized Nuclear Pharmacist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(1) Is certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are

posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Has completed 700 hours in a structured educational program consisting of both:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(B) Supervised practical experience in a nuclear pharmacy involving:

(i) Shipping, receiving, and performing related radiation surveys;

(ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(iv) Using administrative controls to avoid medical events in the administration of byproduct material; and

(v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.57
333-116-0740
Training for Experienced Authorized User, Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Nuclear Pharmacist or Authorized Nuclear Pharmacist

(1) An individual identified on a U.S. Nuclear Regulatory Commission or an Agreement State license or a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of OAR 333-116-0640, 333-116-0905 or 333-116-0910, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this section must meet the training requirements in OAR 333-116-0640(5) or 333-116-0905(3) as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of OAR 333-116-0640 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a U.S. Nuclear Regulatory Commission or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in OAR 333-116-0905 for those materials and uses that these individuals performed on or before October 24, 2005.

(4) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the U.S. Regulatory Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of OAR 333-116-0660 through 333-116-0720.

(5) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of OAR 333-116-0660 through 333-116-0720 those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(a) For uses authorized under OAR 333-116-0300, OAR 333-116-0320, or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) For uses authorized under OAR 333-116-0360, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(c) For uses authorized under OAR 333-116-0420 or OAR 333-116-0480, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(d) For uses authorized under OAR 333-116-0400, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(6) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on U.S. Nuclear Regulatory licenses for the same uses for which these individuals are authorized.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.190
333-116-0660
Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670, 333-116-0680, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680 and 333-116-0740 or U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(4) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (3) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under OAR 333-116-0300.The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in OAR, 333-116-0660, 333-116-0670, 333-116-0680 or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680, or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in section (3) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.204
333-116-0330
Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentration

(1) A licensee must not administer to humans a radiopharmaceutical containing more than 0.15 kBq (0.15 uCi) of molybdenum-99 per MBq (mCi) of technetium-99m; or

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

(3) A licensee that uses molybdenum-99/technetium-99 generators for preparing technetium-99m radiopharmaceuticals must measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with section (1) of this rule.

(4) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with section (1) of this rule.

(5) A licensee who must measure molybdenum concentration or strontium-82 and strontium-85 must retain a record of each measurement in accordance with OAR 333-100-0057. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in MBq (mCi), the measured activity of the molybdenum expressed in kBq (uCi), the ratio of the measures expressed as kBq (uCi) of molybdenum per MBq (mCi) of technetium, the date of the test and the initials of the individual who performed the test.

(6) A licensee must report immediately to the Authority in accordance with OAR 333-116-1011 each occurrence of molybdenum-99 concentration exceeding the limits specified in section (1) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.290
333-116-0660
Training for Uptake, Dilution or Excretion Studies

Except as provided in OAR 333-116-0740, the licensee shall require the authorized user of a radiopharmaceutical listed in OAR 333-116-0300 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an

Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (3)(a)(A) through (3)(b)(F) of this rule; and

(b) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling and quality control; or

(2) Is an authorized user under OAR 333-116-0670, 333-116-0680, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680 and 333-116-0740 or U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects; and

(4) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (3) of this rule and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under OAR 333-116-0300.The attestation must be obtained from either:

(a) A preceptor authorized user who meets the requirements in OAR, 333-116-0660, 333-116-0670, 333-116-0680 or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680, or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in section (3) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.300
33-116-0360
Use of Unsealed Radioactive Materials or Radiopharmaceuticals for Which a Written Directive is Required

A licensee may use any unsealed radioactive material identified in OAR 333-116-0680(2)(b)(F) prepared for medical use for which a written directive is required that is obtained from:

(1) A manufacturer or preparer licensed under OAR 333-102-0285, U.S. Nuclear Regulatory Commission, or equivalent Agreement State requirements; or

(2) A PET radiopharmaceutical producer licensed under OAR 333-102-0190(11) U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements; or

(3) Excluding production of PET radionuclides, prepared by:

(a) An authorized nuclear pharmacist;

(b) A physician who is an authorized user on a license from the Authority, other Agreement State, or the U.S. Nuclear Regulatory Commission and meets the specified requirements in OAR 333-116-0670 or 333-116-0680; or

(c) An individual under the supervision, as specified in OAR 333-116-0100, of the authorized nuclear pharmacist in subsection (3)(a) of this rule or the physician who is an authorized user in subsection (3)(b) of this rule; or

(4) Obtained from and prepared by an Authority, U.S. Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration; or

(5) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.390
333-116-0680
Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required

Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0360 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph (2)(b)(F) of this rule. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses License Toolkit webpage. . To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subsection (2)(a) through paragraph (2)(b)(E) of this rule. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or

(2) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0740, or U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must also have experience in administering dosages in the same dosage category or categories as given in OAR 333-116-0680(2)(b)(F) as the individual requesting authorized user status. The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects in subparagraphs (2)(b)(F)(i) through (iii) within this rule. Radiopharmaceuticals containing radionuclides not listed in subparagraphs (2)(b)(F)(i) through (iii) are regulated under OAR 333-116-0485. This work experience must involve a minimum of three cases in subparagraphs (2)(b)(F)(i) through (iii) within this rule for which the individual is requesting authorized user status.

(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

NOTE: Experience with at least three cases in subparagraph (ii) also satisfies the requirement in subparagraph (i).

(iii) Parenteral administration of any of any radiopharmaceutical that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (2) of this rule and is able to independently fulfill the radiation safety related duties as an authorized user for the medical uses authorized by OAR 333-116-0360 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission, or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0740, equivalent U.S. Nuclear Regulatory Commission, or Agreement State requirements; has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sections (2)(a) and (2)(b) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.392
333-116-0683
Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the U.S. Nuclear Regulatory Commission, or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage; or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(F)(i) or (ii) or 333-116-0687, or equivalent Agreement State requirements; or

(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent NRC or Agreement State requirements. A supervising authorized user who meets the requirements in OAR 333-116-0680(2) must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(i) or (ii). The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and is able to independently fulfill the radiation safety related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under OAR 333-116-0360. The attestation must be obtained from either:

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or (ii); or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; has experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or (ii) and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsections (3)(a) and (3)(b) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.394
333-116-0687
Training for Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries)

Except as provided in OAR 333-116-0740, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (3)(b) of this rule and whose certification has been

recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(F)(ii), or equivalent NRC or Agreement State requirements; or

(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(ii). The work experience must involve:

(A) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(C) Calculating, measuring and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and is able to independently fulfill the radiation duties as an authorized user for the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical use authorized by OAR 333-116-0360 The written attestation must be obtained from either:

(A) A preceptor authorized user who meet the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in OAR 333-116-0687(2)(b)(F)(ii); or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in OAR 333-116-0687(2)(b)(F)(ii), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsections (3)(a) and (3)(b) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.396
333-116-0715
Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(1) Is an authorized user under OAR 333-116-0680 for uses listed in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(2) Is an authorized user under OAR 333-116-0690 or 333-116-0720, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in section (4) of this rule; or

(3) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0690 or 333-116-0720, and who meets the requirements in section (4) of this rule.

(4) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in OAR 333-116-0680(2)(b)(F)(ii).

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in OAR 333-116-0680(2)(b)(F)(iii). A supervising authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715 or U.S. Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(A) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration as specified in OAR 333-116-0680(2)(b)(F)(iii); and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (4) of this rule, and is able to independently fulfill the radiation safety related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be obtained from either:

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent U.S. Nuclear Regulatory or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in section (4) and subsection (4)(b) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.400
333-116-0420
Use of Sources for Manual Brachytherapy

A licensee must use only brachytherapy sources for therapeutic medical uses:

(1) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration and are manufactured, labeled, packaged and distributed under a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State provided that the requirements of OAR 333-116-0140 are met.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.433
333-116-0447
Strontium-90 Sources for Ophthalmic Treatments

(1) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in section (2) of this rule are performed by either:

(a) An authorized medical physicist; or

(b) An individual who:

(A) Is identified as an ophthalmic physicist on:

(i) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or an Agreement State;

(ii) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

(iii) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

(iv) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

(B) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(C) Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(D) Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in OAR 333-116-0445.

(2) The individuals who are identified in section (1) of this rule must:

(a) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under OAR 333-116-0445; and

(b) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in section (1) of this rule will observe treatments, review the treatment methodology, calculate treatment

time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(3) A licensee shall retain a record of the activity of each strontium-90 source in accordance with OAR 333-100-0057.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.490
333-116-0690
Training for Use of Manual Brachytherapy Source

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using manual brachytherapy sources specified in OAR 333-116-0420 for therapy to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of manual brachytherapy; or

(2) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(a) 200 hours of classroom and laboratory training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0690, 333-116-0740 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical facility authorized to use byproduct materials under OAR 333-116-0420. involving:

(A) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material; and

(F) Using emergency procedures to control byproduct material; and

(c) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, or the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (2)(b) of this rule; and

(d) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections(2)(a), (2)(b) and (2)(c) of this rule and is able to independently fulfill the radiation safety related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420. The attestation must be obtained from either:

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0690, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0690, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsections (2)(a), (2)(b) and (2)(c) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.491
333-116-0700
Training for Ophthalmic Use of Strontium-90

Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is an authorized user under OAR 333-116-0690 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(2) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose;

(D) Follow up and review of each individual's case history; and

(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0690, 333-116-0700, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in section (2) of this rule and is able to independently fulfill the radiation safety related duties as an authorized user of strontium-90 for ophthalmic use.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.500
333-116-0400
Use of Sealed Sources for Diagnosis

(1) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(2) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of OAR 333-116-0140(6) are met.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.590
333-116-0710
Training for Use of Sealed Sources for Diagnosis

Except as provided in OAR 333-116-0740 the licensee must require the authorized user using a sealed source in a device specified in OAR 333-116-0400 to be a physician, dentist or podiatrist who:

(1) Is certified by a specialty board whose certification process includes all of the requirements in sections (3) and (4) of this rule and whose certification has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit webpage or:

(2) Is an authorized user for uses listed in OAR 333-116-0320 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(3) Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(a) Radiation physics and instrumentation;

(b) Radiation protections;

(c) Mathematics pertaining to the use and measurement of radioactivity; and

(d) Radiation biology

(4) Has completed training in the use of the device for the uses requested.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.600
333-116-0480
Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

(1) A licensee must only use sealed sources:

(a) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses; or

(b) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of OAR 333-116-0140 are met.

(2) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(a) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of OAR 333-116-0140 are met.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.610
333-116-0495
Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee must:

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(A) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(B) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(C) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by subsection (1)(d) of this rule must be physically located at the unit console.

(3) A licensee must post instructions at the unit console to inform the operator of:

(a) The location of the procedures required by subsection (1)(d) of this rule; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(4) Prior to the first use for patient treatment of a new or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(5) A licensee must provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties in:

(a) The procedures identified in subsection (1)(d) of this rule; and

(b) The operating procedures for the unit.

(6) A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(7) A licensee must retain a record of individuals receiving instruction required by sections (4), (5), and (6) of this rule in accordance with OAR 333-100-0057.

(8) A licensee must retain a copy of the procedures required by subsections (1)(d) and (5)(b) of this rule until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.655
333-116-0600
Safety Checks and Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

(1) A licensee must have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the Nuclear Regulatory Commission or an Agreement State.

(3) If the results of the checks required in section (1) of this rule indicate the malfunction of any system, the licensee must lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(4) A licensee must retain, in accordance with OAR 333-100-0057, a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the Radiation Safety Officer. In addition each record must contain:

(a) The inspector's radioactive materials license number;

(b) The date of inspection;

(c) The manufacturer's name and model number and serial number of both the treatment unit and source;

(d) A list of components inspected and serviced, and the type of service; and

(e) The signature of the inspector.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.690
333-116-0720
Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in OAR 333-116-0740, the licensee must require the authorized user of a sealed source specified in OAR 333-116-0480 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State and who meets the requirements in subsection (2)(c) and section (3) of this rule. The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission’s Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit:

(a) Which includes the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical facility that is authorized to use byproduct materials in OAR 333-116-0480 involving:

(i) Reviewing full calibration measurements and periodic spotchecks;

(ii) Preparing treatment plans and calculating treatment doses and times;

(iii) Using administrative controls to prevent a medical event involving the use of byproduct material;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (2)(a) and (2)(b), and section (3) of this rule, and is able to independently fulfill the radiation safety related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be obtained from either:

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0720 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsections (2)(a) and (2)(b) of this rule.

(3) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.2024, 35.2310, and 35.2655,
333-100-0057
Maintenance of Records

Each record required by this division must be legible throughout the retention period. For the purposes of these rules and unless otherwise specified, records must be retained a minimum of five years. The record may be the original or a reproduced copy or a microfilm provided that the copy or microfilm is authenticated by authorized personnel and that the microfilm is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and 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.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.3045
333-116-1000
Report and Notification of a Medical Event

(1) A licensee must report any medical event as defined in OAR 333-116-0020, except for an event that results from patient intervention in which:

(a) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in;

(A) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(B) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(C) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

(b) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(A) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(B) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(C) An administration of a source that includes any of the following:

(i) The wrong radionuclide;

(ii) The wrong individual or human research subject;

(iii) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(iv) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(2) The licensee must notify by telephone the Authority no later than the next calendar day after discovery of the medical event.

(3) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.

(a) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual(s) who received the administration;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(4) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If

the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

(5) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

For 35.3204
333-116-1011
Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

(1) The licensee shall notify the Authority by telephone at 1-800-452-0311 and request for Radiation Protection Services to call. In addition, the licensee must call the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in OAR 333-116-0330(1) at the time of generator elution. The telephone report to the Authority must include the manufacturer, model number, and serial number (or lot number) of the generator, the results of the measurement, the date of the measurement, whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(2) The licensee shall submit a written report to Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland Oregon, 97232 within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee’s equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee’s breakthrough determination; and the information in the telephone report as required by section (1) of this rule.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807