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

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

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) "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 Department 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.
(4) "Authorized nuclear pharmacist" means a pharmacist who:
(a) Meets the requirements in OAR 333-116-0910 and 333-116-0915; or
(b) Is identified as an authorized nuclear pharmacist on a Department, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or
(c) Is identified as an authorized nuclear pharmacist on a license issued by a Department, 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 Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.
(5) "Authorized user" means a practitioner of the healing arts who:
(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740; or
(b) Is identified as an authorized user on a Department, 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 a Department, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.
(6) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.
(7) "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.
(8) "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.
(9) "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.
(10) "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.
(11) "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.
(12) "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.
(13) "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.
(14) "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.
(15) "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.
(16) "Management" means the chief executive officer or that individual's designee;
(17) "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.
(18) "Medical Event or Medical Error" means an event where a patient or human research subject:
(a) Receives 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; or
(b) Receives a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or
(c) An event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician
(19) "Medical institution" means an organization in which more than one medical discipline is practiced;
(20) "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.
(21) "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.
(22) "Misadministration" means the administration of:
(a) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:
(A) Involving the wrong individual or wrong radiopharmaceutical; or
(B) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceed 1.11 megabecquerels (30 uCi).
(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131;
(A) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
(B) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
(c) A gamma stereotactic radiosurgery radiation dose:
(A) Involving the wrong individual or wrong treatment site; or
(B) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.
(d) A teletherapy radiation dose:
(A) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
(B) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
(C) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
(D) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
(e) A brachytherapy radiation dose:

(A) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
(B) Involving a sealed source that is leaking;
(C) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
(D) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.
(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:
(A) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; or
(B) When the dose to the individual exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.
(23) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.
(24) "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 and 333-116-0915 in the management and handling of radioactive drugs and is authorized by license to receive, use, transfer, and dispose of such radioactive drugs.
(25) "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.
(26) "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.
(27) "PET" means Positron Emission Tomography
(28) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.
(29) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.
(30) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.
(31) "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.
(32) "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.
(33) "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.
(34) "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.

(35) "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.
(36) "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, or a 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 Department, the Nuclear Regulatory Commission, an Agreement State or licensing state.
(37) "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.
(38) "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.
(39) "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.
(40) "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 Commission or Agreement State; or
(B) A medical use permit issued by a Commission master material licensee.
(41) "Recordable Event" (See Medical Event and Misadministration)
(42) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
(43) "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.
(44) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
(45) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
(46) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on a Department license.

(47) "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.
(48) "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.
(49) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
(50) "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 Department as a nuclear pharmacy.
(51) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.
(52) "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).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0027
Implementation
(1) A licensee must implement the provisions in division 333-116 no later June 15, 2006.
(2) When a requirement in division 333-116 differs from the requirement in an existing license condition, the more restrictive requirement must govern until there is a license amendment or license renewal.
(3) Any existing license condition, not affected by a requirement in division 333-116, remains in effect until the license is amended or renewed.
(4) If a license condition exempted a licensee from a provision of division 333-116 on June 15, 2006, it will continue to exempt a licensee from the corresponding provision in division 333-116.

(5) If a license condition cites provisions in division 333-116 that will be deleted on June 15, 2006, then the license condition remains in effect until the license is amended or renewed to modify or remove the condition.
(6) Licensees must continue to comply with any license condition that requires it to implement procedures required by OAR 333-116-0525, 333-116-0580, 333-116-0583, and 333-116-0587 until there is a license amendment or renewal that modifies the license condition.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0035
Application for License, Amendment, or Renewal
(1) An application must be signed by the management of the facility.
(2) An application for a license for medical use of radioactive material as described in OAR 333-116-0200, 333-116-0300, 333-116-0320, 333-116-0360, 333-116-0400, and 333-116-0420 and for medical use of remote afterloaders in 333-116-0480, must be made by filing a "Radioactive Materials License Application: Medical." A request for a license amendment or renewal may be submitted in letter format.
(3) Except for medical use of remote afterloaders, a separate license application must be filed for each medical use of radioactive material as described in OAR 333-116-0480 by filing a "Radioactive Materials License Application: Medical." A request for a license amendment or renewal may be submitted in letter format.
(4) An application for a license for medical use of radioactive material as described in OAR 333-116-0800, Licensing and Registration of Positron Emission Tomography (PET) Facilities, must be made by filing a "Radioactive Materials License Application: Medical."
(a) In addition to the information required in the "Radioactive Materials License Application: Medical," the application must also include information regarding any radiation safety aspects of the medical use of the radioactive material that is not addressed in this division, as well as any specific information necessary for:
(A) Radiation safety precautions and instructions;
(B) Training and experience of proposed users;
(C) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
(D) Calibration, maintenance, and repair of equipment necessary for radiation safety.
(b) The applicant of licensee must also provide any other information requested by the Department in its review of the application.
NOTE: An applicant that satisfies the requirements specified in OAR 333-102-0900 may apply for a Broad Scope A specific license.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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, except a visiting authorized user described in OAR 333-116-0110, to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license. A visiting authorized user is an individual who:
(a) Meets the requirements of 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 or 333-116-0720, 333-116-0740 and 333-116-0760 of these rules; or
(b) Is a nuclear pharmacist who meets the requirements in OAR 333-116-0910 and 333-116-0760; or
(c) Is a medical physicist, who meets the requirements in OAR 333-116-0730, 333-116-0740, 333-116-0760 and 333-116-0905; or
(d) Is identified as an authorized user, or an authorized nuclear pharmacist, 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, respectively, or
(3) Before changing the Radiation Safety Officer or Teletherapy Physicist;
(4) Before receiving radioactive material in excess of the amount authorized on the license;
(5) Before adding to or changing the area of use or mailing address identified on the license; and
(6) Before changing statements, representations and procedures which are incorporated into the license.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0050
Notifications
(1) A licensee must provide to the Department a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, pursuant to OAR 333-116-0040(2)(a) through (d).
(2) A licensee must notify the Department by letter no later than 30 days after:
(a) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change.
(b) The licensee's mailing address changes;
(c) The licensee's name changes, but the name does not constitute a transfer of control of the license as described in OAR 333-102-0305 of these rules; or
(d) The licensee has added to or changed the areas where radioactive material is used in accordance with OAR 333-116-0200 and 333-116-0300.
(3) The licensee must mail the documents required in this division to the Department for review.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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(5) 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, or authorized nuclear pharmacist, and
(5) The provisions of OAR 333-116-0140(1).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0057
License Issuance
(1) The Department must issue a license for the medical use of radioactive material if:
(a) The applicant has filed a "Radioactive Materials License Application: Medical" in accordance with the instructions in OAR 333-116-0035;
(b) The applicant has paid any applicable fee as provided in division 103 of these rules;
(c) The Department finds the applicant equipped and committed to observe the safety standards established by the Department in these rules for the protection of the public health and safety; and
(d) The applicant meets the requirements of division 102 of these rules.
(2) The Department must issue a license for mobile services if the applicant:
(a) Meets the requirements in section (1) of this rule; and
(b) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with OAR 333-116-0460.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0090
Statement of Authorities 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 Department;
(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.
(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 Department 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 division 333-116, 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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0100
Supervision
(1) A licensee who permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by OAR 333-116-0030 must:
(a) In addition to the requirements in OAR 333-111-0010, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, the licensee's written quality management program, the Oregon Rules for the

Control of Radiation and the license conditions appropriate to that individual's use of radioactive material; and
(b) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of division 333-116, and license conditions with respect to the medical use of radioactive material.
(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by OAR 333-116-0030(3) must:
(a) In addition to the requirements in OAR 333-111-0010, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's use of radioactive material; and
(b) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures established by the licensee and division 333-116, and license conditions.
(3) A licensee that permits supervised activities under sections (1) and (2) of this rule is responsible for the acts and omissions of the supervised individual.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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.
(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; 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 remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
(f) For all other 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).

(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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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; and
(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices.
(3) The licensee must retain a copy of procedures in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0110
Visiting Authorized User
(1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:
(a) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;
(b) The licensee has a copy of the Department license or a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, that identifies the visiting authorized user by name as an authorized user for medical use; and
(c) Only those procedures for which the visiting authorized user is specifically authorized by the Department license are performed by that individual.

(2) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in section (1) of this rule.
(3) A licensee must retain copies of the records specified in this rule in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0120
Mobile Nuclear Medicine Service Administrative Requirements
(1) The Department will only license mobile nuclear medicine services in accordance with OAR 333-116-0300, 333-116-0320, and 333-116-0400 of this division and OAR 333-102-0130.
(2) Mobile nuclear medicine service licensees must:
(a) Obtain a letter signed by the management of each client for which services are rendered that authorizes use of licensed radioactive material at the client's address of use. This letter must clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter must document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service. The mobile nuclear medicine service licensee must retain the letter for three years after the last provision of service.
(b) Check instruments used to measure the activity of unsealed byproduct material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function must include a constancy check;
(c) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
(d) Survey all areas of use to ensure compliance with the requirements in division 333-120 before leaving a client's address.
(3) If a mobile nuclear medicine service provides services that the client also is authorized to provide, the client is responsible for assuring that services are conducted in accordance with the rules in this division while the mobile nuclear medicine service is under the client's direction.
(4) A mobile nuclear medicine service may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use unless the client has a radioactive materials license. Radioactive material delivered to the client's address of use must be received and handled in conformance with the client's license.
(5) A mobile medical service licensee must, at a minimum, maintain the following documents onboard each mobile unit:
(a) Current operating and emergency procedures;
(b) Copy of the current license;
(c) Copies of the letter required by section (2) of this rule;
(d) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
(e) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 90 calendar days.

(6) A licensee must retain copies of the records specified in this rule in accordance with OAR 333-100-0057. The records required for subsections (2)(b), (2)(c) and (2)(d) of this rule must include the date of the survey or test, the results of the survey or test, the instrument used to make the survey or source used to perform the test, and the name of the individual who performed the survey or test.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0123
Radiation Safety Program Changes
(1) A licensee may revise its radiation protection program without Department approval if:
(a) The revision does not require a license amendment under OAR 333-116-0040;
(b) The revision is in compliance with the regulations and the license;
(c) The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and, if applicable, the Radiation Safety Committee; and
(d) The affected individuals are instructed on the revised program before the changes are implemented.
(2) A licensee must retain a record of each change in accordance with OAR 333-100-0057. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management, or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0125
Quality Management Program
(1) Each applicant or licensee under this division, as applicable, must establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:
(a) That, prior to administration, a written directive (see NOTE below) is prepared for:
(A) Any teletherapy radiation dose;
(B) Any gamma stereotactic radiosurgery radiation dose;
(C) Any brachytherapy radiation dose;
(D) Any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131; or
(E) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;
(b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(c) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
(d) That each administration is in accordance with the written directive; and
(e) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
NOTE: 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 will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. 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 will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.
(2) The licensee shall:
(a) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:
(A) A representative sample of patient administrations,
(B) All recordable events, and
(C) All misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;
(b) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subsection (2)(a) of this rule; and
(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.
(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:
(a) Assembling the relevant facts including the cause;
(b) Identifying what, if any, corrective action is required to prevent recurrence; and
(c) Retaining a record, in an auditable form, for five years or until inspected by the Department, of the relevant facts and what corrective action, if any, was taken.
(4) The licensee shall retain:
(a) Each written directive; and
(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in subsection (1)(a) of this rule, in an auditable form, for five years, or until inspected by the Department, after the date of administration.
(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The

licensee shall furnish the modification to the Department within 30 days after the modification has been made.
(6) Each applicant for a new license, as applicable, shall submit to the Department in accordance with OAR 333-102-0190 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Department.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0130
Records and Reports of Misadministrations
(1) For a misadministration that meets the definition in OAR 333-116-0020 a licensee must:
(a) Notify the Department by telephone no later than the next calendar day after discovery of the misadministration.
NOTE: The 24-hour phone number of the Department is (971) 673-0490.
(b) The licensee must submit a written report to the Department within 15 days after the discovery of the misadministration. The written report must include:
(A) The licensee's name;
(B) The prescribing physician's name;
(C) A brief description of the event;
(D) Why the event occurred;
(E) The effect on the patient;
(F) What improvements are needed to prevent recurrence;
(G) Actions taken to prevent recurrence; and
(H) Certification that the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.
(c) The licensee must notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee must notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee must not delay medical care for the patient because of this.
(d) If the patient was notified, the licensee also must furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:
(A) A copy of the report that was submitted to the Department; or
(B) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the licensee.

(2) Each licensee must retain a record of each misadministration in accordance with OAR 333-100-0057. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.
(3) Aside from the notification requirement, nothing in this rule must affect any rights or duties of licensees and physicians in relation to each other, patients or responsible relatives or guardians.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

General Technical Requirements

333-116-0150
Quality Control of Imaging Equipment
(1) Each licensee must establish written quality control procedures for all diagnostic equipment used to obtain images from radionuclide studies. As a minimum the quality control procedures and frequencies must include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the Department. The licensee must conduct quality control procedures in accordance with written procedures.
(2) Copies of procedures and records generated from implementing these procedures must be maintained in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0160
Possession, Use, Calibration and Check of Dose Calibrators
(1) A medical use licensee authorized to administer either radiopharmaceuticals or unsealed radioactive materials must possess a dose calibrator and use it to measure the amount of activity of radionuclides prior to administration to each patient or human research subject. The licensee must also develop, implement and maintain written procedures for proper calibration and operation of the dose calibrator.
(2) At a minimum, a licensee must:
(a) Check each dose calibrator for constancy and proper operation with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this rule, the check must be done on a frequently used setting with a sealed source of not less than 1.85 megabecquerels (50 uCi) of any photon-emitting radionuclide with a half-life greater than 90 days. The results of this test must be within +ten percent of the sources stated activity. Sources used for the daily constancy test must be determined by the manufacturer to be within +five percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology.

(b) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different photon-emitting radionuclides 1.85 megabecquerels (50 uCi) each, at least one of which has a principal photon energy between 100 keV and 500 keV. All sources used to satisfy the accuracy test must be determined by the manufacturer to be within +five percent of the stated activity and traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology;
(c) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 megabecquerels (30 microcuries) and the highest dosage that will be administered; and
(d) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee must keep a record of this test for the duration of the use of the dose calibrator.
(3) A licensee must mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.1 megabecquerels (30 microcuries) and must repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
(4) A licensee must also perform checks and tests required by section (2) of this rule following adjustment or repair of the dose calibrator and prior to use.
(5) A licensee must retain a record of each check and test required by section (2) of this rule in accordance with OAR 333-100-0057. The records required by section (2) of this rule must include:
(a) For constancy, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings and the initials of the individual who performed the check;
(b) For accuracy, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings and the signature of the Radiation Safety Officer;
(c) For linearity, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test and the signature of the Radiation Safety Officer; and
(d) For geometry dependence, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test and the signature of the Radiation Safety Officer.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0165
Possession, Use Calibration, and Check of Instruments to Measure Dosages of Alpha- or Beta-emitting Radionuclides
(1) For other than unit dosages, a licensee must possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee must

measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject.
(2) A licensee must develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee must:
(a) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary;
(b) Perform accuracy annually;
(c) Perform linearity tests annually over the range of medical use; and
(d) Check each instrument for constancy and proper operation at the beginning of each day of use.
(3) Accuracy tests must be performed with source(s) that are traceable to National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.
(4) A licensee must retain a record of each check and test required by this rule in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0170
Calibration and Check of Survey Instrument
(1) A licensee must ensure that the survey instruments used to show compliance with OAR chapter 333, divisions 116 and 120 have been calibrated before first use, annually and following repair.
(2) To satisfy the requirements of section (1) of this rule the licensee must:
(a) Calibrate all required scale readings up to ten millisieverts (1000 mrem) per hour with a radiation source;
(b) For each scale that must be calibrated, calibrate two readings separated by at least 50 percent of scale reading; and
(c) Conspicuously note on the instrument the date of calibration.
(3) To satisfy the requirements of section (2) of this rule, the licensee must:
(a) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and
(b) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.
(4) A licensee must check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.
(5) The licensee must retain a record of each calibration required in section (1) of this rule in accordance with OAR 333-100-0057. The record must include:
(a) A description of the calibration procedure; and
(b) A description of the source used and the certified exposure rates from the source and the rates indicated by the instrument being calibrated, the correction factors deduced from

the calibration data, the signature of the individual who performed the calibration and the date of calibration.
(6) To meet the requirements of sections (1), (2) and (3) of this rule, the licensee may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by section (5) of this rule, must be maintained by the licensee calibration in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0180
Determination of Dosages of Unsealed Radioactive Material for Medical Use
A licensee must:
(1) Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 uCi) of an alpha-, beta-, or photon-emitting radionuclide;
(2) For a dosage of an alpha- or beta-emitting radionuclide prepared by the licensee, this determination must be made by direct measurement or by a combination of measurements and calculations.
(3) A licensee must not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent, unless authorized in writing by an authorized user.
(4) Retain a record of the assays required by this rule in accordance with OAR 333-100-0057. The record must contain the:
(a) Generic name, trade name or abbreviation of the radiopharmaceutical, its lot number and expiration dates and the radionuclide;
(b) Patient's name and identification number if one has been assigned;
(c) Prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity is less than 370 kilobecquerels (10 uCi);
(d) Date and time of the assay;
(e) Date and time of administration; and
(f) Initials of the individual who performed the assay.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0190
Authorization for Calibration and Reference Source
Any person authorized by OAR 333-116-0030 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:
(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to OAR 333-102-0290 or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 1.11GBq (30 mCi) each;

(2) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life of 100 days or less in individual amounts not to exceed 1.11GBq (30 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi);
(3) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 milliCi) each; and
(4) Technetium-99m in individual amounts to exceed 1.85 GBq (50 mCi).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0200
Requirements for Possession of Sealed Sources and Brachytherapy Sources
(1) A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department, and must maintain the instructions for the duration of source use in a legible form convenient to users.
(2) A licensee in possession of a sealed source must assure that:
(a) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and
(b) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Department, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry (SS&D).
(3) To satisfy the leak test requirements of this division, the licensee must assure that:
(a) Leak tests are capable of detecting the presence of 185 Bq (0.005 uCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 Bq (0.001 uCi) per 24 hours;
(b) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
(c) For teletherapy units, test samples are taken when the source is in the "off" position.
(4) A licensee must retain leak test records in accordance with OAR 333-100-0057. The records must contain the model number and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (Bq), a description of the method used to measure each test sample, the date of the test and the signature of the Radiation Safety Officer.
(5) If the leak test reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination, the licensee must:
(a) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and
(b) File a report within five days of receiving the leakage test results with the Department describing the equipment involved, the test results and the action taken.
(6) A licensee need not perform a leak test on the following sources:
(a) Sources containing only radioactive material with a half-life of less than 30 days;
(b) Sources containing only radioactive material as a gas;

(c) Sources containing 3.7 MBq (100 uCi) or less of beta or photon-emitting material or 370 kBq (10 uCi) or less of alpha-emitting material;
(d) Seeds of iridium-192 encased in nylon ribbon; and
(e) Sources stored and not being used. The licensee must, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.
(7) A licensee in possession of a sealed source or brachytherapy source must conduct a semi-annual physical inventory of all such sources in its possession. The licensee must retain each inventory record in accordance with OAR 333-100-0057. The inventory records must contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory and the signature of the Radiation Safety Officer.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0250
Surveys for Contamination and Ambient Radiation Dose Rate
(1) A licensee must survey with an appropriate radiation detection survey instrument, at the end of each day of use, all areas where radiopharmaceuticals are routinely prepared for use or administered. Radiation surveys are not required in areas where patients or human research subjects are confined when they cannot be released under OAR 333-116-0260. Radiation surveys are required when patients receive a therapeutic dose or brachytherapy implant and prior to release.
(2) A licensee must survey with an appropriate radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.
(3) A licensee must conduct the surveys required by section (1) and (2) of this rule so as to be able to measure dose rates as low as one Sv (0.1 mrem) per hour.
(4) A licensee must establish dose rate action levels for the surveys required by sections (1) and (2) of this rule and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.
(5) A licensee must survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.
(6) A licensee must conduct the surveys required by section (5) of this rule so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).
(7) A licensee must establish removable contamination action levels for the surveys required by section (5) of this rule and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.
(8) A licensee must retain a record of each survey required by this rule in accordance with OAR 333-100-0057. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in Sv mrem per hour or the removable contamination in each area expressed in Bq (dpm) per 100 square centimeters, the serial

number and the model number of the instrument used to make the survey or analyze the samples and the initials of the individual who performed the survey.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0255
Surveys of Patients and Human Research Subjects Treated With a Remote Afterloader Unit
(1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.
(2) A licensee shall retain a record of these surveys in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0260
Release of Patients Containing Therapeutic Quantities of Radiopharmaceuticals or Permanent Implants
(1) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisieverts (0.5 rem).
(2) The licensee must provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain radiation exposures to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed one millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed one millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:
(a) Guidance on the interruption or discontinuation of breast-feeding; and
(b) Information on the potential consequences, if any, of failure to follow the guidance.
(3) The licensee must maintain a record of the basis for authorizing the release of an individual, for a minimum of five years after the date of release in accordance with OAR 333-100-0057.
(4) The licensee must maintain a record, for a minimum of five years after the date of release, in accordance with OAR 333-100-0057, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding five millisieverts (0.5 rem).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0280

Storage of Volatiles and Gases
(1) A licensee must store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container.
(2) A licensee must store and use a multidose container in a properly functioning fume hood.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0290
Decay-In-Storage
(1) A licensee may hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of OAR 333-120-0500 of these rules if the licensee:
(a) Holds radioactive material for decay a minimum of 10 half-lives;
(b) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument for the radiation being monitored, set on its most sensitive scale and with no interposed shielding;
(c) Removes or obliterates all radiation labels; and
(d) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.
(2) For radioactive material disposed in accordance with these rules the licensee must retain a record of each disposal until inspection by the Department. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container and the name of the individual who performed the survey.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0300
Use of Unsealed Radioactive Material for Uptake, Dilution or Excretion Studies for Which a Written Directive Is Not Required
(1) A licensee may use any unsealed radioactive material for a diagnostic use involving measurements of uptake, dilution or excretion that:
(a) The Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); and
(b) Is obtained from a manufacturer or preparer licensed under OAR 333-102-0285 or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
(c) Is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-0100; or

(d) Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.
(2) A licensee using a radiopharmaceutical specified in section (1) of this rule for a clinical procedure other than one specified in the product label or package insert instructions for use must comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

Imaging and Localization

333-116-0320
Use of Radiopharmaceuticals, Generators and Reagents Kits for Imaging and Localization Studies for Which a Written Directive Is Not Required
(1) A licensee may use any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for:
(a) Which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA); or
(b) Which is prepared and compounded by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in OAR 333-116-0100; or
(c) Obtained from a manufacturer or preparer licensed under divisions 333-102 and 333-116 or equivalent Nuclear Regulatory Commission or Agreement State requirements.
(2) A licensee using radiopharmaceuticals specified in section (1) of this rule for clinical procedures other than one specified in the product label or package insert instructions must comply with the product label or package insert regarding physical form and dosage range.
(3) A licensee must elute generators in compliance with OAR 333-116-0330 and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.
(4) Technetium-99m pentetate as an aerosol for lung function studies is not subject to the restrictions in section (1) of this rule. Provided the conditions of OAR 333-116-0340 are met, a licensee must use radioactive aerosols or gases only if specific application is made to and approved by the Department.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0330
Permissible Molybdenum-99 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.
(2) A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators must measure the molybdenum-99 concentration of the

first eluate after receipt of a generator to demonstrate compliance with section (1) of this rule.
(3) A licensee who must measure molybdenum concentration 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.
(4) A licensee must report immediately to the Department each occurrence of molybdenum-99 concentration exceeding the limits specified in section (1) of this rule.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0370
Safety Instruction
(1) A licensee must provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy who cannot be released under OAR 333-116-0260. Refresher training must be provided at intervals not to exceed one year.
(2) To satisfy section (1) of this rule, the instruction must describe the licensee's procedures for:
(a) Patient or human research subject control;
(b) Visitor control; including
(A) Routine visitation to hospitalized individuals in accordance with OAR 333-120-0180(1)(a); and
(B) Visitation authorized in accordance with OAR 333-120-0180(3).
(c) Contamination control;
(d) Waste control; and
(e) Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency.
(3) A licensee must maintain, in accordance with OAR 333-100-0057, a list of individuals receiving instruction required by section (1) of this rule, a description of the instruction, the date of instruction and the name of the individual who gave the instruction.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0405
Training for Use of Sealed Sources for Diagnosis.
Except as provided in OAR 333-116-0710, the licensee must require the authorized user of a diagnostic sealed source for use in a device authorized under 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 (2) and (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or

(2) 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 protection;
(c) Mathematics pertaining to the use and measurement of radioactivity;
(d) Radiation biology; and
(e) Has completed training in the use of the device for the uses requested.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0425
Surveys After Source Implant and Removal
(1) Immediately after implanting sources in a patient or a human research subject, the licensee must make a survey to locate and account for all sources that have not been implanted.
(2) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must make a survey of the room and the patient or the human research subject with an appropriate radiation detection survey instrument to confirm that all sources have been removed.
(3) A licensee must retain a record of the surveys required by sections (1) and (2) of this rule in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0430
Safety Instructions
(1) The licensee must provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training must be provided at intervals not to exceed one year.
(2) To satisfy section (1) of this rule, the instruction must describe:
(a) Size and appearance of the brachytherapy sources;
(b) Safe handling and shielding instructions in case of a dislodged source;
(c) Procedures for patient control;
(d) Procedures for visitor control including both:
(A) Routine visitation to hospitalized individuals in accordance with OAR 333-120-0180(1)(a); and
(B) Visitation authorized in accordance with OAR 333-120-0180(3); and
(e) Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency.
(3) A licensee must retain a record of individuals receiving instruction required by section (1) of this rule in accordance with OAR 333-100-0057. The record must contain a description of the instruction, the date of instruction and the name of the individual who gave the instruction.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0440
Safety Precaution
(1) A licensee must, for each patient or human research subject receiving implant therapy:
(a) Not place the patient or human research subject in the same room with a patient or human research subject who is not receiving radiation therapy;
(b) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;
(c) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
(d) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with OAR 333-120-0180 of these rules. Retain a record of each survey in accordance with OAR 333-116-0057. Each record must include the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey and the initials of the individual who made the survey; and
(e) Instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.
(2) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
(a) Dislodged from the patient; and
(b) Lodged within the patient following removal of the source applicators.
(3) A licensee must notify the Radiation Safety Officer or authorized user immediately if the patient or human research subject dies or has a medical emergency.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0445
Calibration Measurements of Brachytherapy Sources
(1) Before the first medical use of a brachytherapy source on or after July 1, 2006, a licensee must have:
(a) Determined the source output or activity using a dosimetry system that meets the requirements of OAR 333-116-0560(1);
(b) Determined source positioning accuracy within applicators; and
(c) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of section (1) of this rule.
(2) Instead of a licensee making its own measurements as required in this rule, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with section (1) of this rule.

(3) A licensee must mathematically correct the outputs or activities determined in section (1) of this rule for physical decay at intervals consistent with one percent physical decay.
(4) Only an authorized medical physicist must 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 section (1) of this rule.
(5) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057. Each record must include:
(a) The date of the calibration;
(b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;
(c) The source output or activity;
(d) The source positioning accuracy within the applicators; and
(e) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.
(6) Records of decay of strontium-90 sources for ophthalmic treatments must maintain a record of the activity of a strontium-90 source for the life of the source. The record must include:
(a) The date and initial activity of the source; and
(b) For each decay calculation, the date and the source activity.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0447
Decay of Strontium-90 Sources for Ophthalmic Treatments
(1) Only an authorized medical physicist shall 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.
(2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0450
Brachytherapy Sources Inventory
(1) A licensee must maintain accountability at all times for all brachytherapy sources in storage or use.
(2) As soon as possible after removing sources from a patient or human research subject, the licensee must return brachytherapy sources to a secure storage area.
(3) A licensee must retain the records required in sections (1) and (2) of this rule in accordance with OAR 333-100-0057.
(a) For temporary implants, the record must include:
(A) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
(B) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(b) For permanent implants, the record must include:
(A) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
(B) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and
(C) The number and activity of sources permanently implanted in the patient or human research subject.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0460
Release of Patients Treated with Temporary Implant
(1) Immediately after removing the last temporary implant source from a patient or human research subject, the licensee must make a radiation survey of the patient or human research subject with an appropriate radiation detection survey instrument to confirm that all sources have been removed. The licensee must not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.
(2) A licensee must retain a record of patient surveys which demonstrate compliance with section (1) of this rule in accordance with OAR 333-100-0057. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as Sv (mrem) per hour and measured within one meter from the patient and the initials of the individual who made the survey.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0475
Therapy Related Computer Systems
(1) The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:
(a) The source-specific input parameters required by the dose calculation algorithm;
(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;
(c) The accuracy of isodose plots and graphic displays; and
(d) The accuracy of the software used to determine sealed source positions from radiographic images.
(2) Acceptance testing must be performed when new software is installed, for each software revision and when new computer hardware or treatment planning system hardware is installed or repaired.
(3) Records of acceptance testing must be retained in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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) A licensee must provide instruction, 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.
(5) A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
(6) A licensee must retain a record of individuals receiving instruction required by section (4) of this rule in accordance with OAR 333-100-0057.
(7) A licensee must retain a copy of the procedures required by subsections (1)(d) and (4)(b) of this rule until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0570
Full Calibration Measurement

(1) A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:
(a) Before the first medical use of the unit; and
(b) Before medical use under the following conditions:
(A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
(B) Following replacement of the radioactive source or following reinstallation of the teletherapy unit in a new location;
(C) Following any repair of the teletherapy unit that includes removal of the radioactive source or major repair of the components associated with the source exposure assembly; and
(c) At intervals not exceeding one year.
(2) To satisfy the requirement of section (1) of this rule, full calibration measurements must include determination of:
(a) The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;
(b) The coincidence of the radiation field and the field indicated by the light beam localizing device;
(c) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
(d) Timer accuracy, constancy, and linearity;
(e) On-off error; and
(f) The accuracy of all distance measuring and localization devices in medical use.
(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this rule may then be made using a dosimetry system that indicates relative dose rates.
(4) A licensee must make full calibration measurements required by section (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.
(5) A licensee must correct mathematically the outputs determined in subsection (2)(a) of this rule for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.
(6) Full calibration measurements required by section (1) of this rule and physical decay corrections required by section (5) of this rule must be performed by a teletherapy or medical physicist certified to perform such measurements and named on the licensee's license or authorized by a license issued by the Nuclear Regulatory Commission or an Agreement State to perform such services.
(7) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer

accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device and the signature of the teletherapy physicist.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0573
Full Calibration Measurements on Remote Afterloader Units
(1) A licensee authorized to use a remote afterloader unit for medical use must perform full calibration measurements on each unit:
(a) Before the first medical use of the unit;
(b) Before medical use under the following conditions:
(A) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
(B) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
(c) At intervals not exceeding three months for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
(d) At intervals not exceeding one year for low dose-rate remote afterloader units.
(2) To satisfy the requirement of section (1) of this rule, full calibration measurements must include, as applicable, determination of:
(a) The output within five percent;
(b) Source positioning accuracy to within one millimeter;
(c) Source retraction with backup battery upon power failure;
(d) Length of the source transfer tubes;
(e) Timer accuracy and linearity over the typical range of use;
(f) Length of the applicators; and
(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output.
(4) A licensee must make full calibration measurements required by section (1) of this rule in accordance with published protocols accepted by nationally recognized bodies.
(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in section (2) of this rule, a licensee must perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.
(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with sections (1) through (5) of this rule.
(7) A licensee must mathematically correct the outputs determined in subsection (2)(a) of this rule for physical decay at intervals consistent with one percent physical decay.
(8) Full calibration measurements required by subsection (2)(a) of this rule and physical decay corrections required by subsection (2)(g) of this rule must be performed by the authorized medical physicist.

(9) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0577
Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform full calibration measurements on each unit:
(a) Before the first medical use of the unit;
(b) Before medical use under the following conditions:
(A) Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
(B) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
(C) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
(c) At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
(2) To satisfy the requirement of subsection (1)(a) of this rule, full calibration measurements must include determination of:
(a) The output within +/-three percent;
(b) Relative helmet factors;
(c) Isocenter coincidence;
(d) Timer accuracy and linearity over the range of use;
(e) On-off error;
(f) Trunnion centricity;
(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
(h) Helmet microswitches;
(i) Emergency timing circuits; and
(j) Stereotactic frames and localizing devices (trunnions).
(3) A licensee must use the dosimetry system described in OAR 333-116-0560(1) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (2)(a) of this rule may be made using a dosimetry system that indicates relative dose rates.
(4) A licensee must make full calibration measurements required by section (1) of this rule must be performed in accordance with published protocols accepted by nationally recognized bodies.
(5) A licensee must mathematically correct the outputs determined in subsection (2)(a) of this rule at intervals not exceeding one month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by section (1) of this rule and physical decay corrections required by section (5) of this rule must be performed by the authorized medical physicist.
(7) A licensee must retain a record of each calibration in accordance with OAR 333-100-0057.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0580
Periodic Spot-Checks for Teletherapy Units
(1) A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit at intervals not to exceed one month that include the determination of:
(a) Timer constancy, accuracy, and linearity over the range of use;
(b) On-off error;
(c) The coincidence of the radiation field and the field indicated by the light beam localizing device;
(d) The accuracy of all distance measuring and localization devices used for medical use;
(e) The output for one typical set of operating conditions measured with the dosimetry system described in OAR 333-116-0560; and
(f) The difference between the measurement made in section (1) of this rule and the anticipated output, expressed as a percentage of the anticipated value obtained at last full calibration corrected mathematically for physical decay.
(2) A licensee must use the dosimetry system described in OAR 333-116-0560 to make the measurement required in section (1) of this rule.
(3) A licensee must perform measurements required by section (1) of this rule in accordance with procedures established by the teletherapy or medical physicist. That individual is not required to actually perform the output spot-check measurements.
(4) A licensee must have the teletherapy or medical physicist review the results of each output spot-check within 15 days of each measurement. The teletherapy or medical physicist must promptly notify the licensee in writing of the results of each output spot-check. The licensee must keep a copy of each written notification in accordance with OAR 333-100-0057.
(5) A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility at intervals not to exceed one month and after each source installation to assure proper operation of:
(a) Electrical interlocks at each teletherapy room entrance;
(b) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism;
(c) Beam condition indicator lights on the teletherapy unit, on the control console and in the facility;
(d) Viewing systems;
(e) Treatment room doors from inside and outside the treatment room; and
(f) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(6) A licensee must lock the control console in the "off" position if any door interlock malfunctions. No licensee must use the unit until the interlock system is repaired unless specifically authorized by the Department.
(7) A licensee must promptly repair any system identified in section (5) of this rule that is not operating properly.
(8) A licensee must retain a record of each spot-check required by sections (1) and (5) of this rule in accordance with OAR 333-100-0057. The record must include, the date of the spot-check, the manufacturer's name, model number and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors and the signature of the individual who performed the periodic spot-check.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0583
Periodic Spot-checks for Remote Afterloader Units
(1) A licensee authorized to use a remote afterloader unit for medical use must perform spot-checks of each remote afterloader facility and on each unit:
(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;
(b) Before each patient treatment with a low dose-rate remote afterloader unit; and
(c) After each source installation.
(2) A licensee must perform the measurements required by section (1) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
(3) A licensee must have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.
(4) To satisfy the requirements of section (1) of this rule, spot-checks must, at a minimum, assure proper operation of:
(a) Electrical interlocks at each remote afterloader unit room entrance;
(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
(d) Emergency response equipment;
(e) Radiation monitors used to indicate the source position;
(f) Timer accuracy;
(g) Clock (date and time) in the unit's computer; and

(h) Decayed source(s) activity in the unit's computer.
(5) If the results of the checks required in section (4) of this rule indicate the malfunction of any system, a 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.
(6) A licensee must retain a record of each check required by section (4) of this rule in accordance with OAR 333-100-0057. The record must include, as applicable:
(a) The date of the spot-check;
(b) The manufacturers name, model number for the remote afterloader and source;
(c) An assessment of timer accuracy;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
(7) A licensee must retain a copy of the procedures required by section (4) of this rule until the licensee no longer possesses the remote afterloader unit.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0585
Additional Technical Requirements for Mobile Remote Afterloader Units
(1) A licensee providing mobile remote afterloader service must:
(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
(b) Account for all sources before departure from a client's address of use.
(2) In addition to the periodic spot-checks required by OAR 333-116-0583, a licensee authorized to use mobile afterloaders for medical use must perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
(a) Electrical interlocks on treatment area access points;
(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
(c) Viewing and intercom systems;
(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;
(e) Radiation monitors used to indicate room exposures;
(f) Source positioning (accuracy); and
(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.
(3) In addition to the requirements for checks in section (2) of this rule, a licensee must ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
(4) If the results of the checks required in section (2) of this rule indicate the malfunction of any system, a 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.
(5) A licensee must retain a record of each check required by section (2) of this rule in accordance with OAR 333-116-0057. The record must include:

(a) The date of the check;
(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;
(c) Notations accounting for all sources before the licensee departs from a facility;
(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and
(e) The signature of the individual who performed the check.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0587
Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units
(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use must perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
(a) Monthly;
(b) Before the first use of the unit on a given day; and
(c) After each source installation.
(2) A licensee must:
(a) Perform the measurements required by section (1) of this rule in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
(b) Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist must notify the licensee as soon as possible in writing of the results of each spot-check.
(3) To satisfy the requirements of subsection (1)(a) of this rule, spot-checks must, at a minimum:
(a) Assure proper operation of:
(A) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
(B) Helmet microswitches;
(C) Emergency timing circuits; and
(D) Stereotactic frames and localizing devices (trunnions).
(b) Determine:
(A) The output for one typical set of operating conditions measured with the dosimetry system described in OAR 333-116-0560;
(B) The difference between the measurement made in paragraph (3)(b)(A) of this rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
(C) Source output against computer calculation;
(D) Timer accuracy and linearity over the range of use;
(E) On-off error; and
(F) Trunnion centricity.

(4) To satisfy the requirements of subsections (1)(b) and (1)(c) of this rule, spot-checks must assure proper operation of:
(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
(c) Viewing and intercom systems;
(d) Timer termination;
(e) Radiation monitors used to indicate room exposures; and
(f) Emergency off buttons.
(5) A licensee must arrange for the repair of any system identified in section (3) of this rule that is not operating properly as soon as possible.
(6) If the results of the checks required in section (4) of this rule indicate the malfunction of any system, a 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.
(7) A licensee must retain a record of each check required by sections (3) and (4) of this rule in accordance with OAR 333-100-0057. The record must include:
(a) The date of the spot-check;
(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
(c) An assessment of timer linearity and accuracy;
(d) The calculated on-off error;
(e) A determination of trunnion centricity;
(f) The difference between the anticipated output and the measured output;
(g) An assessment of source output against computer calculations;
(h) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
(i) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
(8) A licensee must retain a copy of the procedures required by section (2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0590
Radiation Surveys Therapeutic Treatment Units
(1) In addition to the survey requirement in OAR 333-120-0200, a person licensed under this rule must make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
(2) The licensee must make the survey required by section (1) of this rule at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(3) A licensee must retain a record of the radiation surveys required by section (1) of this rule for the duration of use of the unit. The record must include:
(a) The date of the measurements;
(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
(d) The signature of the individual who performed the test.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.
(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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0610
Modification of Teletherapy Unit or Room Before Beginning a Treatment Program
(1) If the survey required by OAR 333-116-0590 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in OAR 333-120-0180, before beginning the treatment program the licensee must:
(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with OAR 333-120-0180;
(b) Perform the survey required by OAR 333-116-0590 again; and

(c) Include in the report required by OAR 333-116-0620 the results of the initial survey, a description of the modification made to comply with subsection (1)(a) of this rule, and the results of the second survey.
(2) As an alternative to the requirements set out in subsection (1)(a) of this rule a licensee may request a license amendment under OAR 333-120-0180(3) that authorizes radiation levels in unrestricted areas greater than those permitted by OAR 333-120-0180(1). A licensee may not begin the treatment program until the license amendment has been issued.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0640
Radiation Safety Officer Training and Experience Requirements
Except as provided in OAR 333-116-0650, the licensee shall require an individual fulfilling the responsibilities of the 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 Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
(a)(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 diplomates 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/or 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 Commission or an Agreement State; or
(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0670 and 333-116-0680;
(C) Pass an examination, administered by diplomates 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 a Department, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving 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; or
(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the 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 and who meets the requirements in sections (4) and (5) of this rule; or
(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and
(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in paragraphs (1)(a)(A) and (B) or paragraphs (1)(b)(A) and (B) or section (2) or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and
(5) 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, 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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0660

Training for Uptake, Dilution or Excretion Studies
Except as provided in OAR 333-116-0740 and 333-116-0750, the licensee must 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 includes all of the requirements in section (3) of this rule and whose certification has been recognized by the Commission or an Agreement State; or
(2) Is an authorized user under OAR 333-116-0670 and 333-116-0680 or equivalent Nuclear Regulator Commission or Agreement State requirements; or
(3) Has completed 60 hours of training and experience 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 this rule, OAR 333-116-0670 and 333-116-0680 or Nuclear Regulatory Commission or equivalent Agreement State requirements, involving:
(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 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 radioactive drugs to patients or human research subjects; and
(4) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in this rule, OAR 333-116-0670 and 333-116-0680 or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in section (3) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0300.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0670
Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740 or 333-116-0750, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0320 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 Nuclear Regulatory Commission or an Agreement State; or
(2) Is an authorized user under OAR 333-116-0680 or equivalent Agreement State requirements; or
(3)(a) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum:
(A) 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;
(v) Radiation biology; and
(B) Work experience, under the supervision of an authorized user, who meets the requirements in this rule or OAR 333-116-0680 or equivalent Nuclear Regulatory commission or Agreement State requirements, involving:
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(v) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(vi) Administering dosages of radioactive drugs to patients or human research subjects; and
(vii) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
(b) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0680 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (3)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under this rule or OAR 333-116-0680.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0680

Training for Therapeutic Use of Radiopharmaceuticals
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 includes all of the requirements in section (2) of this rule and whose certification has been recognized by the Commission or an Agreement State; or
(2)(a) Has completed 700 hours of training and experience 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:
(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) Work experience, under the supervision of an authorized user who meets the requirements in sections (1) and (2) of this rule, or Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(a)(B)(vii)(I), (II), (III), (IV)) as the individual requesting authorized user status. The work experience must involve:
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
(vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
(vii) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories 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;
(II) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;
NOTE: Experience with at least three cases in Category (vii)(2) also satisfies the requirement in Category (vii)(A).
(III) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(IV) Parenteral administration of any other radionuclide; and
(b) Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (2)(a) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written certification must be signed by a preceptor authorized user who meets the requirements in sections (1), (2), of this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(a)(B)(vii)(I), (II), (III), or (IV) as the individual requesting authorized user status.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 Nuclear Regulatory Commission or an Agreement State; or
(2) Is an authorized user under OAR 333-116-0680(1) and (2) for uses listed in OAR 333-116-0680(2)(a)(B)(vii)(I) or (II), OAR 333-116-0687, or equivalent Agreement State requirements; or
(3)(a) 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. 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(1) and (2), this rule, OAR 333-116-0687 or Nuclear Regulatory Commission or equivalent 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)(a)(B)(vii)(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 certification that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written certification must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680(1) and (2), this rule, OAR 333-116-0687, or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii)(I) or (II).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0687
Qualifications for Authorized User for Oral Administration When a Written Directive is Required
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)(c) of this rule and whose certification has been recognized by the Commission or an Agreement State; or
(2) Is an authorized user under OAR 333-116-0680(1) and (2) for uses listed in OAR 333-116-0680(2)(a)(B)(vii)(II), or equivalent Nuclear Regulatory commission or Agreement State requirements; or
(3)(a) 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. 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(1) and (2), this rule, or equivalent Nuclear Regulatory Commission 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)(a)(B)(vii)(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 certification that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written certification must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680(1) and (2), this rule, or equivalent Agreement State requirements. A preceptor 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)(a)(B)(vii)(II).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0690
Training for Therapeutic Use of 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 includes all of the requirements in section (2) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or
(2)(a) 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:
(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 this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;
(iii) Preparing, implanting, and removing brachytherapy sources;
(iv) Maintaining running inventories of material on hand;
(v) Using administrative controls to prevent a medical event involving the use of byproduct material;
(vi) Using emergency procedures to control byproduct material; and
(b) Has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this rule or equivalent 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 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 certification, signed by a preceptor authorized user who meets the requirements in this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsections (2)(a) and (2)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 Nuclear Regulatory commission or Agreement State requirements; or
(2)(a) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. 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; and
(D) Follow up and review of each individual's case history; and
(E) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0690, this rule, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in sections (1) and (2) of this rule and has achieved a level of

competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 333-116-0360 for uses listed in OAR 333-116-0680(2)(a)(B)(vii), or equivalent Agreement State requirements; or
(2) Is an authorized user under OAR 333-116-0690 or 333-116-0720, or equivalent Agreement State or Nuclear Regulatory Commission 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 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)(a) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. 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 or this rule, or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in OAR 333-116-0680 must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii). 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, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (4)(b) or (4)(c) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680 or this rule, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680, must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 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 Commission or an Agreement State will be posted on the NRC's 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 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 diplomates 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)(a) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
(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 this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:
(i) Reviewing full calibration measurements and periodic spot-checks;
(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 this rule or equivalent 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 (1)(a) or (2)(a) and (2)(b), and section (3) of this rule, and has achieved a level of competency sufficient to function independently 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 signed by a preceptor authorized user who meets the requirements in this rule or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and
(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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of OAR 333-116-0640 through 333-116-0760 and OAR 333-116-0905 through 333-116-0915.

(2) Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a Department, Nuclear Regulatory Commission or Agreement State or Licensing State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of OAR 333-116-0640 through 333-116-0760.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0760
Recentness of Training
The training and experience specified in OAR 333-116-0640 through 333-116-0730 and OAR 333-116-0905 through 333-116-0915 must have been obtained within the seven years preceding the date of application or the individual must have had continuing education and experience since the required training and experience was completed.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

Specific Requirements for Positron Emission Tomography (PET) Facilities

333-116-0830
Accelerator Facility Requirements
(1) Accelerators must meet all requirements of division 333-109. Shielded-room accelerators must be equipped with interlocks and personnel control; self-shielded accelerators must be shielded such that personnel access is prevented during operation.
(2) Non-ionizing radiation must meet requirements of division 333-112.
(3) Target maintenance and repair, contamination control, and emergency actions must be conducted pursuant to division 333-120.
(4) There must be an Understanding of Transfer (UOT) when isotopes are transferred from one licensee or entity to another for processing, specifying at what point control is transferred to personnel handling radiochemical production or radiopharmacy operation.
(5) Radiation surveys must be made prior to any accelerator operation or isotope production with a radiation survey instrument calibrated in accordance with requirements in OAR 333-116-0390. Periodic surveys must be done throughout times of operation to ensure that radiation levels meet all applicable requirements in division 333-120 (Radiation Protection Standards).
(6) Ventilation controls must be implemented to ensure compliance with all applicable local, state, and federal requirements. Controls must include monitoring of stacks and computer modeling of air emissions to confirm compliance with standards.
(7) Real-time (integrating) monitors must be used to confirm requirements in OAR 333-120-0100, 333-120-0160, 333-120-0170, and 333-120-0180.
(8) Contamination wipes for radioactive material must be made pursuant to requirements in OAR 333-116-0250;
(9) Dosimetry must address both gamma and beta doses in all areas of the facility. Licensees and registrants must monitor extremities to ensure compliance with OAR 333-120-0100. Bioassays, as defined in OAR 333-100-0005, are not required, but there must

be evaluation of internal exposures, pursuant to OAR 333-120-0130, based on calculated releases and monitoring.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0840
Safety Considerations and Quality Management for PET Facilities
(1) The licensee must establish and implement a Quality Management program pursuant to OAR 333-116-0125 for PET products, as well as other production and calibration products.
(2) PET instrumentation and other equipment unique to the PET process must meet all applicable radiation protection standards pursuant to division 120 of these rules.
(3) Area monitors must be visible and audible to accelerator operators. Monitors must be checked for proper operation daily.
(4) Wasted targets must be treated as radioactive waste and must be properly dismantled, shielded, stored, and disposed.
(5) Accelerator shielding design and safety must meet requirements of OAR 333-109-0025.
(6) Shielding around guide-bends, targets, hot-cells, purification manifolds, etc. must ensure that limits in OAR 333-120-0180 and OAR 333-120-0190 have been met in all areas of beam and nuclide production.
(7) Security provisions for unauthorized access, janitorial services, maintenance, visitors, tours, and personnel-in-training must conform to requirements in OAR 333-120-0180, 333-120-0250 and 333-120-0260.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0870
Rubidium-82 Generator
Rubidium-82 generators require quality assurance procedures for equipment, patient injection, waiting area, imaging, and post-imaging care. There also must be a procedure for spills, and a handling procedure for liquid quality assurance sources for early model PET cameras. Dose calibration procedures are the same as in OAR 333-116-0850(6).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0880
Training and Experience for PET, PET/CT and SPECT/CT Personnel
(1) Pharmacy or chemistry personnel must have 40 extra hours above Nuclear Pharmacy requirements and 40 hours specific to PET. The 40 hours should be divided equally between didactic and practical applications.
(2) Authorized users who meet training requirements for human use in OAR 333-116-0670 must complete an additional 40 hours at an accepted PET training center.
(3) Technical personnel working under an authorized user must have basic radiation safety training, plus 40 additional hours specific to PET.

(4) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems must be operated by:
(a) Any registered radiographer with the credential R.T. (R); or
(b) Registered radiation therapist with the credential R.T. (T); and
(c) Who are currently licensed by the Oregon Board of Radiologic Technology; or
(d) Registered certified nuclear medicine technologist with the credentials R.T. (N); or
(e) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).
(5) The individuals mentioned in section (4) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.
(6)(a) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Department; and
(b) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or
(c) Individuals meeting the requirements of section (4) of this rule and who have successfully completed training that the Department has evaluated and judged to be substantially equivalent to that specified in subsection (6)(a) of this rule.
(7) An R.T. (N) or CNMT certified in Computed Tomography through the American Registry of Radiologic Technologists is considered to have met the training requirements in section (4) of this rule.
(8) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 Commission or an Agreement State and who meets the requirements in subsection (2)(b) and section (3) of this rule. 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/or supervised experience in medical physics:
(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the 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 333-116-0720 or 333-116-0730; 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)(a) 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. 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 subsections (1)(a) and (1)(b) and section (3) of this rule, or subsection (2)(a) and section (3) of this rule, and has achieved a level of competency sufficient to function independently 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, or equivalent 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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

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 Commission or an Agreement State and who meets the requirements in subsection

(2)(b) of this rule. 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 diplomates 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 subsections (1)(a), (1)(b), and (1)(c) or (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-0915
Training for Experienced Nuclear Pharmacists
A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in OAR 333-116-0910(2)(a) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in

OAR 333-116-0910(2)(b) and recentness of training in OAR 333-116-0760 to qualify as an authorized nuclear pharmacist.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-1015
Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child
(1) A licensee must report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
(2) A licensee must report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual who:
(a) Is greater than 50 mSv (5 rem) total effective dose equivalent; or
(b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
(3) The licensee must notify the Department by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.
(4) The licensee must submit a written report to the Department within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.
(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 embryo/fetus or the nursing child;
(F) What actions, if any, have been taken or are planned to prevent recurrence; and
(G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.
(5) The licensee must provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under sections (1) or (2) of this rule, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this rule, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee must inform the

mother, or the mother's or child's 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.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807

333-116-1030
Report of a Leaking Source
A licensee must file a report with the Department within five days if a leak test required by OAR 333-116-0200 reveals the presence of 185 Bq (0.005 uCi) or more of removable contamination. The written report must include:
(1) The model number and serial number of the leaking source, if assigned;
(2) The radionuclide and its estimated activity;
(3) The results of the test;
(4) The date of the test; and
(5) The action taken.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 through 453.807