Oregon
Theodore R. Kulongoski, Governor

Department of Human Services
Public Health Division
Environmental Public Health
Radiation Protection Services
800 NE Oregon Street, Suite 640
Portland, OR 97232-2162

March 1, 2010

Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Reis:

Enclosed is a copy of the final revisions to the State of Oregon, Radiation Protections Services Section, Oregon Administrative Rules. The grayed area found in the attached compatibility chart show the changes made created by the comments received from the first review. These final revisions have been submitted to the State of Oregon, Secretary of State Office for final rules.

Rats ID	Title	State Section
• 2006-1	Minor Amendments	333-120-0015

We believe that adoption of these rules satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (971) 673-0500 or email me @ Todd.s.carpenter@state.or.us

Sincerely,

Todd S. Carpenter
Licensing Manager

Final Published Rule Revision for RATS 2006-1
Final Oregon Administrative Rules
Minor Amendments

Part 32.72
333-102-0285
Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Division 116
(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter will be approved if:
(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;
(b) The applicant submits evidence that the applicant is at least one of the following:
(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
(B) Registered or licensed with a state agency as a drug manufacturer;
(C) Licensed as a pharmacy by a state Board of Pharmacy; or
(D) Operating as a nuclear pharmacy within a federal medical institution.
(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and
(d) The applicant satisfies the following labeling requirements:
(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.
(B) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.
(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:
(a) May prepare radioactive drugs for medical use, as defined in OAR 333-116-0020, provided that the radioactive drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(c) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.
(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:
(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

(B) This individual meets the requirements specified in OAR 333-116-0910, 333-116-0760, 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

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

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Part 32.79

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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 32.72
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 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 32.74
333-102-0290
Manufacture and Distribution of Sources or Devices Containing Byproduct Material for Medical Use

(1) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to division 116 of this chapter for use as a calibration transmission or reference source or for the uses listed in OAR 333-116-0400, 333-116-0420 and 333-116-0480 will be approved if:

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

(b) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(A) The radioactive material contained, its chemical and physical form and amount;

(B) Details of design and construction of the source or device;

(C) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(D) For devices containing radioactive material, the radiation profile of a prototype device;

(E) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(F) Procedures and standards for calibrating sources and devices;

(G) Legend and methods for labeling sources and devices as to their radioactive content; and

(H) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device. Provided, that instructions that are too lengthy for such a label may be summarized on the label and printed in detail on a brochure that is referenced on the label.

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, date of assay and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in OAR 333-116-0190, 333-116-0400, or 333-116-0420, as appropriate, and to persons who hold an equivalent license issued by an Agreement State or the US Nuclear Regulatory Commission. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months:

(a) The applicant must include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(b) In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

(A) Primary containment or source capsule;
(B) Protection of primary containment;
(C) Method of sealing containment;
(D) Containment construction materials;
(E) Form of contained radioactive material;
(F) Maximum temperature withstood during prototype tests;
(G) Maximum pressure withstood during prototype tests;
(H) Maximum quantity of contained radioactive material;
(I) Radiotoxicity of contained radioactive material; and
(J) Operating experience with identical sources or devices similarly designed and constructed sources or devices.
Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

Part 35.2
333-116-0020
Definitions
As used in this division, the following definitions apply:
(1) "Address of use" means the building or buildings identified on the license as the location(s) where radioactive material may be received, used, or stored.
(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.
(3) “Attestation” means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission’s form 313A.
(4) "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.
(5) "Authorized nuclear pharmacist" means a pharmacist who:
(a) Meets the requirements in OAR 333-116-0910 and 333-116-0915;
(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;
(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.
(6) "Authorized user" means a physician, dentist or podiatrist who:
(a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;
(b) Is identified as an authorized user on 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.
(7) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.
(8) "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.
(9) "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.
(10) "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.
(11) "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.
(12) "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.
(13) "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.
(14) "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.
(15) "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.

(16) "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.
(17) "Management" means the chief executive officer or that individual's designee.
(18) "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.
(19) "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;
(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.
(20) "Medical institution" means an organization in which more than one medical discipline is practiced.
(21) "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.
(22) "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.
(23) "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.
(24) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.
(25) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 333-116-0910 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.
(26) "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.
(27) "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.
(28) "PET" means Positron Emission Tomography.
(29) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.
(30) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.
(31) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.
(32) "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.

(33) "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.
(34) "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.
(35) "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.
(36) "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.
(37) "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.
(38) "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.
(39) "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.
(40) "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.
(41) "Radiation Safety Officer" means an individual who:
(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or
(b) Is identified as a Radiation Safety Officer on:
(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or
(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.
(42) "Recordable Event" (See Medical Event and Misadministration).

(43) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
(44) "Stereotactic Radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.
(45) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.
(46) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
(47) "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on a Department license.
(48) "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.
(49) "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.
(50) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
(51) "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Department as a nuclear pharmacy.
(52) "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.
(53) "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:
(a) For any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131: the dosage;
(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
(d) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
(e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
(f) For all other brachytherapy:
(A) Prior to implantation: the radioisotope, number of sources, and source strengths; and
(B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Part 35.49
333-116-0140
Suppliers
A licensee may use for medical use only:
(1) Radioactive material manufactured, produced, labeled, prepared, compounded, packaged and distributed in accordance with a license issued pursuant to these rules or the equivalent rules of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.
(2) Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.
(3) Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the state Board of Pharmacy.
(4) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission.
(5) Sealed sources or devices non-commercially transferred from a 10 CFR, Part 35 licensee or Agreement State medical licensee.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Part 35.50
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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

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

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

(1) Is certified by a specialty board whose certification process has been recognized by the 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, 333-116-0690, 333-116-0720 or 333-116-0740; 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

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meets the requirements in this rule, 10 CFR part 35 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 - 453.807

35.59
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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

35.100
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, 333-116-0670 and 333-116-0670(3)(B); 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.

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(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 - 453.807

Part 35.190
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, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:
(a) Classroom and laboratory training in the following areas:
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(b) Work experience, under the supervision of an authorized user who meets the requirements in 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 attestation, 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 - 453.807

Part 35.190
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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 35.200
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 penetrate 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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 35.290
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, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies. 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 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 attestation, 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 - 453.807

Part 35.300
333-116-0360
Use of Unsealed Radioactive Materials or Radiopharmaceuticals for Which a Written Directive is Required
A licensee may use for therapeutic administration any unsealed radioactive material or radiopharmaceutical prepared for medical use that:
(1) Has been granted acceptance or approval by the Food and Drug Administration; and
(2) Has been prepared by an authorized nuclear pharmacist, a physician who is an authorized user on a license from the Department, other Agreement State, or the U.S. Nuclear Regulatory Commission and meets the specified requirements in OAR 333-116-0670; or
(3) Has been manufactured and distributed under a license from the Department, other Agreement State, or the U.S. Nuclear Regulatory Commission; or

(4) Obtained from and prepared by the Department or Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or
(5) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Part 35.390
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 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 35.392
333-116-0683
Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)
Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:
(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State; or
(2) Is an authorized user under OAR 333-116-0680 section (1) or (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 section (1) or (2), 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 attestation 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 attestation 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 - 453.807

35.394
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 section (1) or (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 section (1) or (2), 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 attestation 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 attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680 section (1) or (2), 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 - 453.807

35.396
333-116-0715

Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

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

(1) Is an authorized user under OAR 333-116-0360 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 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

Part 35.490
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; and
(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 attestation, 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

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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 - 453.807

Part 35.491
333-116-0700
Training for Ophthalmic Use of Strontium-90
Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:
(1) Is an authorized user under OAR 333-116-0690 or equivalent 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;
(D) Follow up and review of each individual's case history; and
(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0690, 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 - 453.807

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Part 35.491
333-116-0700
Training for Ophthalmic Use of Strontium-90
Except as provided in OAR 333-116-0740, the licensee must require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:
(1) Is an authorized user under OAR 333-116-0690 or equivalent 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:

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(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and
(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
(A) Examination of each individual to be treated;
(B) Calculation of the dose to be administered;
(C) Administration of the dose;
(D) Follow up and review of each individual's case history; and
(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0690, 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 - 453.807

Part 35.690
333-116-0720

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

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

(1) Is certified by a medical specialty board whose certification process has been recognized by the 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 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

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Minor Amendments- Part 20, 30, 32, 35, 40, and 70
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06
Date Due For State Adoption 03/27/09

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
20. Appendix B	Standards For Protection Against Radiation "List of Elements"		A	In Appendix B to Part 20, ''List of Elements,'' the Element ''Thalium,'' Atomic Number 69, should be changed to read as ''Thulium.''	No		OAR refers to appendix B part 20. no changes necessary. Refers throughout Division 102
20. Appendix D	Standards For Protection Against Radiation "United States Nuclear Regulatory Commission Regional Offices"		D	N/A	N/A		
§ 30.6	Communications		D	N/A	N/A		
§ 32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.		B	**In § 32.72, paragraph (b)(2)(ii) is revised to read as follows:** (b) * * * (2) * * * (ii) This individual meets the requirements specified in 10 CFR 35.55(b) and 35.59 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or * * * *			32.72 is compatible to 333-102-0285. **Added per NRC final comment. Reference to 333-116-0760 (Recentness of Training) to 333-116-0285(2)(B)** 35.55 compatible with 333-116-0910 35.59 compatible with 333-116-0760

§ 32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use.		B	**In § 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, and 35.600 of this chapter will be approved if: * * * * *			Add terms byproduct and transmission to 333-102-0290(1)
§ 35.2	Definitions		B	*Authorized medical physicist* means an individual who— (1) Meets the requirements in §§ 35.51(a) and 35.59; or			Meets 333-116-0020(4)
§ 35.2	Definitions		B	*Authorized nuclear pharmacist* means a pharmacist who— (1) Meets the requirements in §§ 35.55(a) and 35.59; or			Meets 333-116-0020(5)
§ 35.2	Definitions		B	*Authorized user* means a physician, dentist, or podiatrist who— (1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or			Meets 333-116-0020(6)
§ 35.2	Definitions		B	*Radiation Safety Officer* means an individual who— (1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or			Meets 333-116-0020(41)
§ 35.2	Definitions		D	*Medical event*	N/A		

§ 35.8	Information collection requirements: OMB approval.		D	N/A	N/A		
§ 35.10	Implementation		D	N/A	N/A		
§ 35.13	License Amendments		D	N/A	N/A		
§ 35.14	Notifications		D	N/A	N/A		
§ 35.49	Suppliers for sealed sources or devices for medical use.		C	**In § 35.49, paragraph (b) is revised to read as follows:** (b) Sealed sources or devices noncommercially transferred from a Part 35 licensee or an Agreement State medical use licensee.			New rule: 333-116-0140(5)
§ 35.50	Training for Radiation Safety Officer.		B	**In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:** (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290 or 35.390;			Meets 333-116-0640
§ 35.51	Training for an authorized medical physicist.		B	**In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * * (ii) In clinical radiation facilities			Meets 333-116-0905

				providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, 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 § 35.51, 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 * * * * *			**Meets 333-116-0905(B)** **Added per NRC final comment.** **Deleted 333-116-0730** **Added 333-116-0690** **333-116-0720** **333-116-0740** Meets 333-116-0905
§ 35.59	Recentness of training.		B	**Section 35.59 is revised to read as follows:** The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the seven years preceding the date of application or the individual			Meets 333-116-0760

				must have had related continuing education and experience since the required training and experience was completed.			
§ 35.65	Authorization for calibration, transmission, and reference sources.		D	N/A	N/A		
§ 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.		H&S	**In § 35.100, paragraph (b)(2) is revised to read as follows:** b) * * * (2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			Meets 333-116-0300(c) **Added per NRC final comment.** **Added 333-116-0670 and 333-116-0670(3)(B)**
§ 35.190	Training for uptake, dilution, and excretion studies.		B	**In § 35.190, paragraphs (b), (c)(1)(ii) and (c)(2) are revised to read as follows:** (b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or **(c)(1)*** * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving— * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or equivalent Agreement State			Meets 333-116-0660(3) Meets 333-116-0600(E)(b) Meets 333-116-0660(4)

				requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.			
§ 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.		H&S	**In § 35.200, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in § 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			Meets 333-116-0320(b)
§ 35.290	Training for imaging and localization studies.		B	**In § 35.290, paragraphs (a)(1), (b), the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (a) * * * (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and * * * * * (b) Is an authorized user under § 35.390 and meets the requirements in 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or			Meets 333-116-0670(3)

				(c)(1) * * * (ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involving— * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.			Meets 333-116-0360(B)(b)
§ 35.300	Use of unsealed byproduct material for which a written directive is required.		H&S	**In § 35.300, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or * *			Meets 333-116-0360 **Added per NRC final comment.** **Added 333-116-0360(2) "meets specified requirements in OAR 333-116-0690**

§ 35.390	Training for use of unsealed byproduct material for which		B	**In § 35.390, paragraphs (b)(1)(ii) introductory text, (b)(1)(ii)(G)(3), and (b)(2) are revised to read as follows:** (b)(1) * * *			

	a written directive is required.			(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experiencein administering dosages in the same dosage category or categories (*i.e.*,35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve— * * * * * (G) * * * (*3*) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or * * * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.390 or equivalent Agreement State requirements.			Meets 333-116-0715(4)(b) Meets 333-116-0715(4)(b) 333-116-0715(4)(b) Meets 333-116-0715(c) Meets 333-116-0715(c)

				The preceptor authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
§ 35.392	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).		B	**In § 35.392, paragraph (b), the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*1*) or (*2*), § 35.394, or equivalent Agreement State requirements; or (c) * * *(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has			Meets 333-116-0680(2) Meets 333-116-0680(b) Meets 333-116-0687(c)

				achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*).			
§ 35.394	Training for the oral administration of sodium iodide I−131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).		B	**In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*2*) or equivalent Agreement State requirements; or (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified			Meets 333-116-0687(2) Meets 333-116-0687(b)

				in § 35.390(b)(1)(ii)(G)(*2*). The work experience must involve— * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*2*).			333-116-0687(c)
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.		B	**In § 35.396, the introductory paragraph, paragraphs (a), (b), (c), the introductory text of paragraphs (d)(1) and (d)(2), paragraph (d)(2)(vi), and paragraph (d)(3) are revised to read as follows:** Except as provided in § 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who— (a) Is an authorized user under § 35.390 for uses listed in §§			Meets 333-116-0715 Meets 333-116-0715(1)(2)(3)(4)

				35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements; or (b) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section. (d)(1) 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— * * * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta			Meets 333-116-0715(4)(b)

				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 § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*). The work experience must involve— * * * * *			Meets 333-116-0715(F)
				(vi) Administering dosages to patients or human research subjects, that include at least 3 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 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, 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			Meets 333-116-0715(4)(c)

				written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*).			
§ 35.490	Training for use of manual brachytherapy sources.		B	**In § 35.490, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 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			**Meets 333-116-0690. Oregon states it meets 333-116-0720 which is incorrect.** **Meets 333-116-0690(2)(B)** **Meets 333-116-0690(2)(b)**	

Deleted: Meets 333-116-0720(B)

Deleted: Meets 333-116-0720(2)(b)¶

Deleted: Meets 333-116-0720(2)(b)¶

				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 (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section 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 § 35.400.			**333-116-0690(2)(c)** **The meaning of certification has been changed to attestation**
35.491	Training for ophthalmic use of strontium-90.		B	**In § 35.491, paragraphs (a) and (b)(3) are revised to read as follows:** (a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or(b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or equivalent Agreement State			Meets 333-116-0700(2)(b)(E)

Deleted: Meets 333-116-0720(c)¶

				requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.		B	**In § 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or, equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690 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 Royal College of Physicians and Surgeons of Canada or the			Meets 333-116-0720(2)(b) 333-116-0720(1)(a)

				Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, 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 § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and * * * * *			Meets 333-116-0720(2)(c)
§ 40.5	Communications		D	N/A	N/A		
§ 70.5	Communications		D	N/A	N/A		
§ 70.14	Foreign military aircraft		D	N/A	N/A		