333-102-0285 for RATS 2018-1; Part 32.72

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Byproduct Material for Medical Use Under Division 116

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter may 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 the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(B) Registered or licensed with a state agency as a drug manufacturer;

(C) Licensed as a pharmacy by a state Board of Pharmacy;

(D) Operating as a nuclear pharmacy within a federal medical institution; or

(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radiopharmaceutical drugs by medical use licensees; and

(d) The applicant commits~~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 radiopharmaceutical 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 radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceutical 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 radiopharmaceutical 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 radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;

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

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

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

(d) May designate a pharmacist (as defined in OAR 333-116-0020) as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radiopharmaceutical drugs containing accelerator-produced radioactive material; and

(B) The individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission.

(e) Shall provide to the Authority a copy of:

(A) Each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910. ~~with the written attestation signed by a preceptor as required by OAR 333-116-0680(2)(b); or~~

(B) The Commission or Agreement State license; or

(C) Commission master materials licensee permit; or

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

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

(F) 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 (2)(b)(C) of this rule, which allows the individual to work as an authorized nuclear pharmacist.

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

(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.

(c) A licensee shall satisfy the labeling requirements in section (1)(d) of this rule.

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

NOTE: Although the Authority 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 Authority for use by persons licensed for medical use pursuant to OAR chapter 333, division 116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory Commission or any other Agreement State, may submit the pertinent information specified in this rule.

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

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

333-102-0305 for RATS 2018-1; Part 30.34

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

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

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

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

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

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

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

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

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

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

(b) Protect restricted data; and

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

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

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

333-116-0020 for RATS 2018-1; Part 35.20
Definitions

As used in this division, the following definitions apply:

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

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

(3) “Associate Radiation Safety Officer” means and individual who:

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

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

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

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

(2019) "Medical Event" means an event that meets the criteria in OAR 333-116-1000. ~~where a patient or human research subject: (a) Receives a dose that differs from the prescribed dose by:~~

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

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

~~(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or~~

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

~~(E) An administration of a wrong radiopharmaceutical drug containing radioactive material; or~~

~~(F) An administration of a radiopharmaceutical drug containing radioactive material by the wrong route of administration; or~~

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

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

~~(I) 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).~~

~~(b) 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 shall be considered as a medical event.~~

~~(c) A leaking sealed source shall be considered as a medical event.~~

(26) “Ophthalmic physicist” means an individual who:

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

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

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

(B) Permit issued by a U.S. Nuclear Commission, Authority, or U.S. Nuclear Regulatory Commission broad scope medica use licensee.

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

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

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

~~(41) "Recordable Event" (See Medical Event).~~

333-116-0040 for RATS 2018-1; Part 35.13
License Amendments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

333-116-0050 for RATS 2018-1; Part 35.14
Notifications

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

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

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

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

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

(b) A copy of the U.S. Nuclear Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at

all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

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

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

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

(c) The licensee's mailing address changes;

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

(e) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either OAR 333-116-0300 or 333-116-0320 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; or

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

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

~~(1) A licensee must provide to the Authority a copy of the board certification, the Nuclear Regulatory Commission or Agreement State license, or the permit issued by a licensee of Broad Scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, or an authorized nuclear pharmacist pursuant to OAR 333-116-0040(2)(a) through (d).~~

~~(2) A licensee must notify the Authority by letter no later than 30 days after:~~

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

~~(b) The licensee's mailing address changes;~~

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

~~(d) The licensee has added to or changed the areas where radioactive material is used in accordance with OAR 333-116-0200 and 333-116-0300.~~

~~(3) The licensee must mail the documents required in this division to the Authority for review.~~

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

333-116-0055 for RATS 2018-1; Part 35.15
Exemptions Regarding Type A~~a~~ Specific Licenses of Broad Scope

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

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

(2) The provisions of OAR 333-116-0040(5) regarding additions to or changes in areas of use only at the addresses specified in the license;

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

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

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

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

333-116-0090 for RATS 2018-1; Part 35.24
Authority and Responsibilities for the Radiation Protection Program

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

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

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

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

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

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

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

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

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

(a) Identify radiation safety problems;

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

(c) Stop unsafe operations; and

(d) Verify implementation of corrective actions.

(7) Licensees that are authorized for two or more different types of uses of radioactive material under OAR chapter 333, division 116, must establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an

authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

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

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

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

333-116-0105 for RATS 2018-1; Part 35.40
Written Directives

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

(a) If, because of the emergent nature of the patient's condition , a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

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

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

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

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

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

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

(f) For permanent implant ~~all other~~ brachytherapy:

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

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

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

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

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

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

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

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

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

333-116-0107 for RATS 2018-1; Part 35.41
Procedures for Administrations Requiring a Written Directive

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

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

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

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

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

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

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

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

~~(d) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices.~~

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

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

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

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

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 U.S. Nuclear Regulatory Commission.

(5) Sealed sources or devices non-commercially transferred from a 10 CFR, Part 35 licensee or Agreement State medical licensee.

(6) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under chapter 333, division 102 or equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State.

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

333-116-0330 for RATS 2018-1; Part 35.204
Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentration

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

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

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

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

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

(6) A licensee must report immediately to the Authority in accordance with OAR 333-116-0330 each occurrence of molybdenum-99 concentration exceeding the limits specified in section (1) of this rule.

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

History:

333-116-0360 for RATS 2018-1; Part 35.300
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 identified in OAR 333-116-0680(2)(b)(F) ~~or radiopharmaceutical~~ prepared for medical use for which a written directive is required that is obtained from: ~~that:~~

(1) A manufacturer or preparer licensed under OAR 333-102-0285, U.S. Nuclear Commission, or equivalent Agreement State requirements; or ~~Has been granted acceptance or approval by the Food and Drug Administration; and~~

(2) A PET radiopharmaceutical producer licensed under OAR 333-102-0190(10(a)(N), U.S. Nuclear Commission or equivalent Agreement State requirements; or

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

(a) ~~Has been prepared by~~ A~~a~~n authorized nuclear pharmacist;

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

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

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

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~~(3) Has been manufactured and distributed under a license from the Authority, other Agreement State, or the U.S. Nuclear Regulatory Commission; or~~

~~(4) Obtained from and prepared by the Authority 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~~

(4~~5~~) Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

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

History:

333-116-0400 for RATS 2018-1; Part 35.500
Use of Sealed Sources for Diagnosis

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

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

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

~~A licensee must only use sealed sources for diagnostic medical use as approved in the Sealed Source and Device Registry.~~

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

333-116-0420 for RATS 2018-1; Part 35.400
Use of Sources for Manual Brachytherapy

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

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

(2) In research with an active Investigational Device Exemption (IDE) application accepted by the Food and Drug Administration and are manufactured, labeled, packaged and distributed

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under a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State provided that the requirements of OAR 333-116-0140 are met.

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

333-116-0447 for RATS 2018-1; Part 35.433
~~**Decay of**~~ **Strontium-90 Sources for Ophthalmic Treatments**

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

(a) An authorized medical physicist; or

(b) An individual who:

(A) Is identified as an ophthalmic physicist on a specific medical use license issued by the U.S. Nuclear Commission or an Agreement State; permit issued by a U.S. Nuclear Commission or Agreement State broad scope medical use licensee; medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or permit issued by a U.S. Nuclear Commission master material licensee broad scope medical use permittee; and

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

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

(D) Has documented training in:

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

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

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

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

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

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

~~(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under OAR 333-116-0445.~~

(3~~2~~) A licensee shall retain a record of the activity of each strontium-90 source in accordance with OAR 333-100-0057.

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

333-116-0480 for RATS 2018-1; Part 35.600
Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

(1) A licensee must only use sealed sources:

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

~~(1) As approved in the Sealed Source and Device Registry; or~~

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

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

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

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

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

333-116-0495 for RATS 2018-1; Part 35.610
Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(1) A licensee must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) The operating procedures for the unit.

(6~~5~~) A licensee must ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

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

(7) A licensee must retain a copy of the procedures required by subsections (1)(d) and (5~~4~~)(b) of this rule until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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

333-116-0600 for RATS 2018-1; Part 35.655
Safety Checks and Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

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

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

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

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

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

(b) The date of inspection;

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

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

(e) The signature of the inspector.

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

333-116-0640 for RATS 2018-1; Part 35.50
Radiation Safety Officer and Associate Radiation Safety Officer Training and Experience Requirements

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

(1) Is certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule.

(a) ~~(~~The names of board certifications which have been recognized by the U.S. Nuclear Commission or an Agreement State are posted on the U.S. Nuclear Commission's Medical Uses Licensee Toolkit web page.~~NRC's webpage.)~~ 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 diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

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

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Authority ~~,~~ ~~Agreement~~or Agreement State license, ~~Licensing State~~ or permit issued by a U.S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a U.S. Nuclear

Commission, Authority's or an Agreement State license or permit issued by a U.S. Nuclear Regulatory master material licensee. The full-time radiation safety experience must involve the following: ~~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; and~~or~~

(h) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in sections (2) and (5) of this rule, and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or an Associate Radiation safety Officer, and ~~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 a Authority, U.S. Nuclear Regulatory Commission or an Agreement State license, a permit issued by a U.S. Regulatory Commission master material license broad scope permittee, ~~the licensee's~~ ~~licens~~e and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual as the ~~has~~ Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in section (5) of this rule; or ~~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~~

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~~(1)(a)(A) and (1)(b)(B) or paragraphs (1)(b)(A) and (1)(b)(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, Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

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

333-116-0660 for RATS 2018-1; Part 35.190
Training for Uptake, Dilution or Excretion Studies

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

(1) Is certified by a medical specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page ~~and who meets the requirements in section (4) of this rule (The names of board certifications recognized by the NRC or an Agreement State are posted on the NRC's website).~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

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

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

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

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

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

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

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

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

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

(b) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR, 333-116-0660, 333-116-0670, 333-116-0680, or 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation

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Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.

~~(4) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements, in OAR 333-116-0740, 333-116-0660, 333-116-0670, or 333-116-0680, or Nuclear Regulatory Commission or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or 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 333-116-0300.~~

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

333-116-0670 for RATS 2018-1; Part 35.290
Training for Imaging and Localization Studies

Except as provided in OAR 333-116-0740, 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 has been recognized by the U.S. Nuclear Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page ~~and who meets the requirements in section (4) of this rule. (The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's website).~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

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(a) 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 as described in subsection (3)(a) through paragraph (2)(b)(G) of this rule; and

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

(2) Is an authorized user under OAR 333-116-0680 and meets the requirements in OAR 333-116-0670(3)(b)(G) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(3) 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.

(a) The training and experience must include at a minimum 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 or OAR 333-116-0670, 333-116-0680, 333-116-0740 and 333-116-0670(3)(b)(G) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0740 or 333-116-0910 may provide the supervised work experience for subsection (3)(b)(B) of this rule. , Work experience must involve: ~~involving:~~

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

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

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

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

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

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

(G) Eluting generator systems appropriate for preparation of radiopharmaceutical drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

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

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and 333-116-0320. The attestation must be obtained from either:~~, signed by a preceptor authorized user who meets the requirements in this rule or OAR 333-116-0670(3)(b)(G), 333-116-0680, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a) or 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 and 333-116-0320.~~

(a) A preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0670 or 333-116-0680 and subsection (3)(b)(G) of this rule or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

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

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

333-116-0680 for RATS 2018-1; Part 35.390
Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required

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

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

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subsection (2)(a) through paragraph

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(2)(b)(E). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0068, 333-116-0740,~~740~~, ~~and sections (1) and (2) of this rule,~~ or U.S. Nuclear Regulatory Commission ~~NRC~~ or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must also have experience in administering dosages in the same dosage category or categories as given in OAR 333-116-0680(2)(b)(F) as the individual requesting authorized user status. The work experience must involve:

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

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

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

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

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

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

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

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

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

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

~~(iv) Parenteral administration of any other radionuclide; and~~

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in section~~s (1) and~~ (2) of this rule ~~and paragraph (2)(b)(F) of this rule,~~ and is able to independently fulfill the radiation safety related duties as an authorized user for the medical uses authorized by OAR 333-116-0360 for which the individual is requesting authorized user status. The attestation must be obtained from either: ~~has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in 333-116-0740, 333-116-0680 or equivalent NRC or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in 333-116-0680(2)(b)(F)(i), (ii), (iii), or (iv) as the individual requesting authorized user status.~~

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

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(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized

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

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

333-116-0683 for RATS 2018-1; Part 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)

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

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

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

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(E) Radiation biology; and

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

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently fulfill the radiation safety related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under OAR 333-116-0360. The attestation must be obtained from either: ~~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 333-116-0740, 333-116-0680, 333-116-0683, 333-116-0687 or equivalent NRC or Agreement State requirements. A preceptor authorized user, who meets the requirement in OAR 333-116-0680(2), must also have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or (ii).~~

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

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR, 333-116-0680, 333-116-0683, 333-116-0687, 333-

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116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. Has experience in administering dosages as specified in OAR 333-116-0680 (2)(b)(F)(i) or (ii) and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in sections (3)(a) and (3)(b) of this rule.

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

333-116-0687 for RATS 2018-1; Part 35.394
Training for Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 1.22 Gigabecquerels (33 millicuries)

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

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

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

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

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and is able to independently fulfill the radiation duties as an authorized user for the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical use authorized by OAR 333-116-0360 ~~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 obtained from either: ~~signed by a preceptor authorized user who meets the requirements in 333-116-0680, 333-116-0687, 333-116-0740, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 333-116-0680(2), must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(ii).~~

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

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in OAR 333-116-0687(2)(b)(F)(ii), and concurs with the attestation provided by the residency program director. The residency training program

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must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (3)(a) and (3)(b) of this rule.

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

333-116-0690 for RATS 2018-1; Part 35.490
Training for Use of Manual ~~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 has been recognized by the U.S. Nuclear Regulatory Commission ~~NRC~~ or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission~~,~~ or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit web page. ~~and who meets the requirements in subsection (2)(d) of this rule. (The names of board certifications which have been recognized by the NRC or an Agreement State are posted on the NRC's webpage.)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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(D) Radiation biology; and

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

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

(B) Checking survey meters for proper operation;

(C) Preparing, implanting and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

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

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

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

(d) Has obtained written attestation, ~~signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent NRC or Agreement State requirements~~, that the individual has satisfactorily completed the requirements in subsections (1)(a), or subsections (2)(a), (2)(b) and (2)(c) of this rule and is able to independently fulfill the radiation safety related duties ~~has achieved a level of competency sufficient to function independently~~ as an authorized user of manual brachytherapy sources for the medical uses authorized under 333-116-0420. The attestation must be obtained from either:

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

(B) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in OAR 333-116-0690, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be

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approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsections (2)(a), (2)(b) and (2)(c) of this rule.

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

333-116-0700 for RATS 2018-1; Part 35.491
Training for Ophthalmic Use of Strontium-90

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

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

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

(A) Examination of each individual to be treated;

(B) Calculation of the dose to be administered;

(C) Administration of the dose;

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

(E) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0690, 333-116-0700, 333-116-0740, ~~333-116-0690, 333-116-~~

~~0700~~, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in section (2) of this rule and is able to ~~has achieved a level of competency sufficient to function~~ independently fulfill the radiation safety related duties as an authorized user of strontium-90 for ophthalmic use.

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

333-116-0710 for RATS 2018-1; Part 35.590
Training for Use of Sealed Sources for Diagnosis

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

(1) Is certified ~~in~~ by a specialty board whose certification process includes all of the requirements in sections (2) and (4) of this rule and whose certification has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory's Medical Uses Licensee Toolkit web page or:

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protections;

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

(d) Radiation biology

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

~~(a) Radiology, diagnostic radiology with special competence in nuclear radiology, radiation oncology or therapeutic radiology by the American Board of Radiology; or~~

~~(b) Nuclear medicine by the American Board of Nuclear Medicine; or~~

~~(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology.~~

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~~(2) Has completed eight hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training must include:~~

~~(a) Radiation physics, mathematics pertaining to the use and measurement of radioactivity and instrumentation;~~

~~(b) Radiation biology;~~

~~(c) Radiation protection and training in the use of the device for the purposes authorized by the license; and~~

~~(d) Training in the use of the device for the uses requested.~~

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

333-116-0715 for RATS 2018-1; Part 35.396
Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive

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

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

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

(4) The physician h~~H~~as successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in OAR 333-116-0680 (2)(b)(F)(ii).~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, or parenteral administration of any other radionuclide for which a written directive is required.~~

(a) 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;

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in OAR 333-116-0680(2)(b)(F)(iii).~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, 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, 333-116-0715 or U.S. Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. ~~as specified in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv).~~ The work experience must involve:

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

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

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

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

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

(F) Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration as specified in OAR 333-116-(2)(b)(F)(iii); and, ~~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 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 sections (2) or (3) of this rule, and is able to ~~and has achieved a level of competency sufficient to function~~ independently fulfill the radiation safety related duties as an authorized user for the parenteral administration of unsealed byproduct material ~~as an authorized~~

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~~user for the parenteral administration of unsealed byproduct material~~ requiring a written directive. The written attestation must be obtained from either: ~~signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 333-116-0680, must have experience in administering dosages as specified in 333-116-0680(2)(b)(F)(iii) or 333-116-0680(2)(b)(F)(iv).~~

(A) A preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in OAR 333-116-0360, 333-116-0715 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

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

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

333-116-0720 for RATS 2018-1; 35.690
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 U.S. Nuclear Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's ~~NRC's~~ Medical Uses Licensee Toolkit web page. webpage.~~)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

(a) Which includes the following:

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical facility~~institution~~ that is authorized to use byproduct materials in OAR 333-116-0480~~,~~ 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 OAR 333-116-0720, 333-116-0740 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 is able to independently fulfill the radiation safety related duties as ~~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~~ an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be obtained from either: ~~signed by a preceptor authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 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~~

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

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

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

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

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333-116-0740 for RATS 2018-1; Part 35.57

Training for Experienced Authorized User, Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Nuclear Pharmacist or Authorized Nuclear Pharmacist

~~(1) An individual identified as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 need not comply with the training requirements of OAR 333-116-0640, 333-116-0905 or 333-116-0910.~~

~~(2) Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Authority, Nuclear Regulatory Commission or Agreement State or Licensing State license before July 1, 2006 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements OAR 333-116-0640, 333-116-0905, or 333-116-0910. .~~

~~(3) Individuals who need not comply with training requirements as described in this rule may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

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

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

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, X-ray and radium physics, or radiological

physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in OAR 333-116-0905 for those materials and uses that these individuals performed on or before October 24, 2005.

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

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

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

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

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

(d)) For uses authorized under 333-116-0400, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation

oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

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

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

333-116-0905 for RATS 2018-1; Part 35.51
Training for Authorized Medical Physicist

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

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

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

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

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

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

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

(2) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

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

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

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

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

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (2~~1~~)(a) and (2~~1~~)(a~~b~~) of this rule, ~~or subsection (2)(a)~~ and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, OAR 333-116-0740, 333-116-0905, or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

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

333-116-0910 for RATS 2018-1; Part 35.55
Training for an Authorized Nuclear Pharmacist

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

(1) Is certified by a specialty board whose certification process has been recognized by the U.S. Nuclear Commission or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Commission or an Agreement State are posted on the U.S. Nuclear Commission's Medical Uses Licensee Toolkit web page. ~~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 diplomats of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

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

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

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

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

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

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

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

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

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

(b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (21)(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.

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

333-116-0915
Training for Experienced Nuclear Pharmacists

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in OAR 333-116-0910(2)(a) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in 333-116-0910(2)(b) and recentness of training in 333-116-0760 to qualify as an authorized nuclear pharmacist.

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

333-116-1000 for RATS 2018-1; Part 35.3045
Report and Notification of a Medical Event

(1) A licensee must report any medical event as defined in OAR 333-116-0020(19), except for an event that results from patient intervention in which:

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

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

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

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

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

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

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

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

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

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

(v) A leaking sealed source.

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

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

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

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

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

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

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

(i) The wrong radionuclide;

(ii) The wrong individual or human research subject;

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

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

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

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

(a) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

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

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

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

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

(4) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

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

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

333-116-1010 for RATS 2018-1; Part 35.3204
Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

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

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

333-125-0080
Background Investigations and Access Control Program: Procedures for Processing of Fingerprint Checks

(1) For the purpose of complying with OAR 333-125-0020 through 333-125-0095, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, Attn: Criminal History Program/Mail Stop – T-07D04M, ~~Criminal History Program, Division of Facilities and Security,~~ 11545 Rockville Pike, ~~Mail Stop T-7D04M, Rockville,~~ Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by electronic mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.

(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513. Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)

(3) The Commission shall forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.635
History:

333-125-0180 for RATS 2018-2; Part 37.77
Physical Protection in Transit: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

(1) As specified in sections (1) and (2) of this rule, each licensee shall provide advance notification to the Authority and the Governor of a state, or the Governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

(a) Procedures for submitting advance notification. The notification must be made to the Authority and to the office of each appropriate Governor or Governor's designee. The contact information, including telephone and mailing addresses, of Governors and Governors' designees, is available on the NRC's website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

(b) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(c) A notification delivered by any means other than mail must be received ~~reach NRC~~ at least four days before the transport of the shipment commences and must reach the office of the Governor or the Governor's designee at least four days before transport of a shipment within or through the state.

(2) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

(a) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

(b) The license numbers of the shipper and receiver;

(c) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(d) The point of origin of the shipment and the estimated time and date that shipment will commence;

(e) The estimated time and date that the shipment is expected to enter each state along the route;

(f) The estimated time and date of arrival of the shipment at the destination; and

(g) A point of contact, with a telephone number, for current shipment information.

(3)(a) Revision notice. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Governor of the state or the Governor's designee and to the Authority.

(b) A licensee shall promptly notify the Governor of the state or the Governor's designee of any changes to the information provided in accordance with sections (2) and (3) of this rule. The licensee shall also immediately notify the Authority. ~~NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes.~~

(4) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the Governor of each state or to the Governor's designee previously notified and to the Authority. The licensee shall send the cancellation notice before the shipment has commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(5) Records. The licensee shall retain a copy of the advance notification, any revision and cancellation notices as a record for three years after the notification has been made.

(6) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the U.S. Nuclear Regulatory Commission or an Agreement State, who receive schedule information of the kind specified in section (2) of this rule shall protect that information against unauthorized disclosure as specified in OAR 333-125-0120.

Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.635
History: