PUBLIC HEALTH DIVISION
Radiation Protection Services
John A. Kitzhaber, MD, Governor

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January 28, 2013

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

Dear Ms. Henderson:

Enclosed is a copy of the State of Oregon, Radiation Protections Services Section, final Administrative Rules as filed with Oregon Secretary of State. These final revisions are scheduled to go into effect January 29, 2013.

Rats ID

2009-1, Part 35, Medical Use of Byproduct Material – Authorized User Clarification

State Section: Oregon Administrative Rules (OAR) Chapter 333, Division 116

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

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

Sincerely,

Todd S. Carpenter
Licensing Manager

Cc: Kathleen Schneider

Enclosures: Copy of final Oregon Administrative Rules

CFR 35.50 for OAR 333-116-0640

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 Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

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

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

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

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

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

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

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving the following:

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

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

(C) Securing and controlling byproduct material;

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

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

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

(G) Disposing of radioactive material; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in sections (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of

similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in subsections (1)(a)(A) and (1)(b)(B) or subsections (1)(b)(A) and (1)(b)(B) or (2), or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

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

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

CFR 35.51 for OAR 333-116-0905

Training for Authorized Medical Physicist

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

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) and section (3) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740, , 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 (1)(a) and (1)(b)), 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, in OAR, 333-116-0740, 333-116-0905 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

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

an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

35.57 for OAR 333-116-0740

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

(1) An individual identified as a Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license before July 1, 2006 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 a 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.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

35.190 for OAR 333-116-0660

Training for Uptake, Dilution or Excretion Studies

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

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State 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:

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

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

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0660, 333-116-0670, 333-116-0680 and 333-116-0740 or 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, signed by a preceptor authorized user who meets the requirements, in OAR 333-116-0740, 333-116-0660, 333-116-0670, or333-116-0680, 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 OAR 333-116-0300.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

35.290 for OAR 333-116-0670

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 Commission or an Agreement State 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:

(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 Nuclear Regulatory Commission or 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 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, 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. .

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

CFR 35.390 for OAR 333-116-0680

Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required

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

(1) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in section (2)(b)(G) and (2)(C) of this rule. (Specialty boards whose certification processes have been recognized by the Nuclear Regulatory Commission or an Agreement

State will be posted on the Nuclear Regulatory Commission's Web page). 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 Sections (2) and (2)(b). 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 diplomates 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 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 333-116-0740, and sections (1) and (2) of this rule, or Nuclear Regulatory Commission or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(b)(G) 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;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radiopharmaceutical drugs; and

(G) Administering dosages of radiopharmaceutical drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

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

NOTE: Experience with at least three cases in Category (vii)(2) also satisfies the requirement in Category (vii)(A).

(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(iv) Parenteral administration of any other radionuclide; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (1) and (2) and (2)(b)(G) 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 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in sections OAR 333-116-0740, 333-116-0680 or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories (i.e., OAR 333-116-0680(2)(b)(G)(i), (ii), (iii), or (iv) as the individual requesting authorized user status.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

CFR 35.392 for OAR 333-116-0683

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

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

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in section 3(c) or this rule. (The names of board certidications which have been recognized by the Nuclear Regulatory Commission or an Ageement State will be posted on the Nuclear Regulatory Commission's Web page; or

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

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

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR ,333-116-0740, 333-116-0680, 333-116-0687, of this rule, or equivalent Nuclear Regulatory Commission 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)(G) (ii).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

CFR 35.394 for OAR 333-116-0687

Qualifications for Authorized User for Oral Administration When a Written Directive is Required

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

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) (3)(b) of this rule and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the Nuclear Regulatory Commission or an Agreement State will be posted on the Nuclear Regulatory Commission Web page.);2; or

(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680 subsection (2)(b)(G)(ii), or equivalent Nuclear Regulatory commission 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 Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680. The work experience must involve:

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740 , or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680(2)(a), must have experience in administering dosages as specified in OAR 333-116-0680(2)(a)(B)(vii)(II).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

CFR 35.396 for OAR 333-116-0715

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

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

(1) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(G)(iii) or 333-116-0680(2)(b)(G)(iv) or equivalent Agreement State requirements; or

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

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

(4)Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV,

and/or parenteral administration of any other radionuclide for which a written directive is required.

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680 333-116-0715, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in OAR 333-116-0680 must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(G)(iii) and/or 333-116-0680(2)(b)(G)(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, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least three cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (2) or (3) of this rule, of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0715, 333-116-0740 or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in OAR 333-116-0680, must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(G))(iii) and/or 333-116-0680(2)(b)(G)(iv).

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

CFR 35.490 for OAR 333-116-0690

Training for Therapeutic Use of Brachytherapy Source

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

(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (2) of this rule. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

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

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

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

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical 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 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 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

(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 Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a), or subsections (2)(b) and (2)(c) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420.

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10

CFR 35.491 for OAR 333-116-0700

Training for Ophthalmic Use of Strontium-90

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

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

(2) 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 333-116-0740, 333-116-0690, 333-116-0700, or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

CFR 35.690 for OAR 333-116-0720

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

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

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

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

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

(2) 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 333-116-0720, OAR 333-116-0740, , or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

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

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

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

(v) Checking and using survey meters; and

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

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 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 has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 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

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

Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08