333-116-0020 for RATS 2018-1, Part 35.2
Definitions

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

(a) Meets the requirements in OAR 333-116-0640 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.

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

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

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

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

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

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

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

(f) For permanent implant brachytherapy:

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

(B) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, total source strength implanted, and the date; or

333-116-0660 for RATS 2018-1, Part 35.290
Training for Uptake, Dilution or Excretion Studies

(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;

(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. An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0740 or OAR 333-116-0910 may provide the supervised work experience for paragraph (3)(b)(G) of this rule involving:

(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 and OAR 333-116-0320. The attestation must be obtained from either:

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

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

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

(a) The training must include:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

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

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

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

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

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

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

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

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and is able to independently fulfill the radiation duties as an authorized user for the oral administration of greater than 1.22

gigabecquerels (33 millicuries) of sodium iodide I-131 for medical use authorized by OAR 333-116-0360 The written attestation must be obtained from either:

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

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

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

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

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

(b) The licensee permits an individual qualified to be a Radiation Safety Officer under OAR 333-116-0640 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;