

OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

PERMANENT ADMINISTRATIVE ORDER

PH 75-2024

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
10/11/2024 9:52 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Corrections to Radioactive Materials program rules for compatibility with Nuclear Regulatory Commission's federal regulations

EFFECTIVE DATE: 10/29/2024

AGENCY APPROVED DATE: 10/08/2024

CONTACT: Todd Carpenter
503-572-8870
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St. Suite 640
Portland, OR 97232

Filed By:
Public Health Division
Rules Coordinator

RULES:

333-116-0640, 333-116-0740, 333-116-0910, 333-125-0001, 333-125-0080

AMEND: 333-116-0640

NOTICE FILED DATE: 08/21/2024

RULE SUMMARY: OAR 333-116-0640 is being amended by changing the term "U.S. Nuclear Regulatory master material license" to "U.S. Nuclear Regulatory master material licensee" to recognize an entity rather than a license document.

CHANGES TO RULE:

333-116-0640

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 or an individual assigned duties and tasks as an Associate 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 Regulatory Commission or an Agreement State and who meets the requirements in section (4) of this rule.¶
- (a) The names of board certifications which 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 webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:¶
 - (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 U.S. Nuclear Regulatory 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 U.S. Nuclear Regulatory Commission, ~~Authority~~Oregon Health Authority (Authority) or Agreement State license, 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 Regulatory 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: ¶
- (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.¶
- (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 (4) 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 meets the requirements in section (4) of this rule; or¶
- (b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on an Authority, U.S. Nuclear Regulatory Commission, or an Agreement State license, a permit issued by a U.S. Nuclear Regulatory Commission, Authority licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory master material licensee broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in section (4) of this rule. ¶
- (4) 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

AMEND: 333-116-0740

NOTICE FILED DATE: 08/21/2024

RULE SUMMARY: OAR 333-116-0740 is being amended by changing the term from "by a U.S. Nuclear Regulatory Commission master material license of broad scope" to "in accordance with a Commission master material broad scope license." The amended rule will recognize the correct federal regulation title.

CHANGES TO RULE:

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 on a U.S. Nuclear Regulatory Commission or an Agreement State license or a permit issued by a U.S. Nuclear Regulatory 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 section 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.¶

(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. ¶

(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 ~~in accordance with a Commission master material license of broad scope license~~ 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;¶

(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 OAR 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 rule 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

AMEND: 333-116-0910

NOTICE FILED DATE: 08/21/2024

RULE SUMMARY: OAR 333-116-0910 is being amended by changing the term "American Council on Pharmaceutical Education" to "Accreditation Council on Pharmacy Education" to correct the title of a specialty board that is recognized by the Nuclear Regulatory Commission.

CHANGES TO RULE:

333-116-0910

Training for an Authorized Nuclear Pharmacist ¶¶

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

(1) Is certified by a specialty board whose certification process has been recognized by the 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 Commission's Medical Uses Licensee Toolkit webpage. 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 Accreditation 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 subsection (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

AMEND: 333-125-0001

NOTICE FILED DATE: 08/21/2024

RULE SUMMARY: OAR 333-125-0001 is being amended by removing subsection (2)(h) within the rule, which directs the licensee to report their radioactive sources to the National Source Tracking System by January 31, 2009. Previous rulemaking now requires the licensee to report annually to the tracking system. This section of this rule is antiquated.

CHANGES TO RULE:

333-125-0001

Nationally Tracked Sources ¶¶

(1) Purpose and Scope. This rule outlines the reporting requirements for any licensees that possess an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37 to report to the National Source Tracking System (NSTS). The mission of the NSTS is to track category 1 and category 2 radioactive materials from manufacturing through their disposal, decay, or exportation.¶¶

(2) Reports of Transactions. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in subsections (2)(a) through (2)(e) of this rule for each type of transaction.¶¶

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction report. The report must include the following information:¶¶

- (A) The name, address, and license number of the reporting licensee;¶¶
- (B) The name of the individual preparing the report;¶¶
- (C) The manufacturer, model, and serial number of the source;¶¶
- (D) The radioactive material in the source;¶¶
- (E) The initial source strength in becquerels (curies) at the time of manufacture; and¶¶
- (F) The manufacture date of the source.¶¶

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction report. The report must include the following information:¶¶

- (A) The name, address, and license number of the reporting licensee;¶¶
- (B) The name of the individual preparing the report;¶¶
- (C) The name and license number of the recipient facility and the shipping address;¶¶
- (D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the sources;¶¶
- (E) The radioactive material in the source;¶¶
- (F) The initial or current source strength in becquerels (curies);¶¶
- (G) The date for which the source strength is reported;¶¶
- (H) The shipping date;¶¶
- (I) The estimated time of arrival date; and¶¶

(J) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked sources.¶¶

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:¶¶

- (A) The name, address, and license number of the reporting licensee;¶¶
- (B) The name of the individual preparing the report;¶¶
- (C) The name, address, and license number of the person that provided the source;¶¶
- (D) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;¶¶
- (E) The radioactive material in the source;¶¶
- (F) The initial or current source strength in becquerels (curies);¶¶
- (G) The date for which the source strength is reported;¶¶
- (H) The date of receipt; and¶¶

(I) For material received under a Uniform Low-Level radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.¶¶

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:¶¶

- (A) The name, address, and license number of the reporting licensee;¶¶
- (B) The name of the individual preparing the report;¶¶
- (C) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely

identify the source;¶

(D) The radioactive material in the source;¶

(E) The initial or current source strength in becquerels (curies);¶

(F) The date for which the source strength is reported; and¶

(G) The disassemble date of the source.¶

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:¶

(A) The name, address, and license number of the reporting licensee;¶

(B) The name of the individual preparing the report;¶

(C) The waste manifest number;¶

(D) The container identification with the nationally tracked source;¶

(E) The date of disposal; and¶

(F) The method of disposal.¶

(f) The reports discussed in subsections (2)(a) through (2)(e) of this rule must be submitted by the close of the next business day after the transactions. The report must be submitted to the National Source Tracking System by using:¶

(A) The online National Source Tracking System;¶

(B) Electronically using a computer readable format;¶

(C) By facsimile;¶

(D) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or¶

(E) By telephone with follow up by facsimile or mail.¶

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by subsections (2)(a) through (2)(e) of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.¶

~~(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (2)(f)(A) through (2)(f)(E) of this rule. The initial inventory report must include the following information:¶~~

~~(A) The name, address, and license number of the reporting licensee;¶~~

~~(B) The name of the individual preparing the report;¶~~

~~(C) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;¶~~

~~(D) The radioactive material in the sealed source;¶~~

~~(E) The initial or current source strength in becquerels (curies); and¶~~

~~(F) The date for which the source strength is reported.~~

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.635

AMEND: 333-125-0080

NOTICE FILED DATE: 08/21/2024

RULE SUMMARY: OAR 333-125-0080 is being amended by inserting the city of Rockville within the address to submit fingerprint cards in section (1) of the rule since the city name was previously omitted.

CHANGES TO 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, 11545 Rockville Pike, Attn: Criminal History Program/Mail Stop - T-07D04M, 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 electronic mail at MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/security/chp.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 Division of Physical and Cyber Security Policy by electronic mail at Crimhist.Resource@nrc.gov. 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 Licensee Criminal History Records Checks & Firearms Background Check information page at <https://www.nrc.gov/security/chp.html> and see the link for "How do I determine how much to pay for the request?" ¶¶

(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