



PERMANENT ADMINISTRATIVE ORDER

FILED

01/17/2023 12:39 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

PH 3-2023

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Radiation Protection Services, Radioactive Materials Program – proposed amendments for Title 10, CFR compatibility

EFFECTIVE DATE: 01/18/2023

AGENCY APPROVED DATE: 01/09/2023

CONTACT: Todd Carpenter
971-673-0500
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St. Suite 640
Portland, OR 97232

Filed By:
Public Health Division
Rules Coordinator

RULES:

333-102-0350, 333-105-0560, 333-105-0700, 333-105-0740, 333-113-0210, 333-116-0680, 333-116-0690, 333-116-0720, 333-116-1000, 333-116-1015, 333-118-0070, 333-120-0450, 333-120-0700, 333-120-0710, 333-121-0320, 333-125-0025, 333-125-0080, 333-125-0120, 333-125-0125, 333-125-0180

AMEND: 333-102-0350

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-102-0350 is amended by providing the reporting party the 24-hour notification phone number to contact the Authority.

CHANGES TO RULE:

333-102-0350

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Reporting Requirements ¶¶

(1) Immediate report. Each licensee must notify the Authority as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc. or other manmade and natural events). ¶¶

(2) Twenty-four hour report. Each licensee must notify the Authority within 24 hours after the discovery of any of the following events involving licensed material: ¶¶

(a) An unplanned contamination event that: ¶¶

(A) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; ¶¶

(B) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and ¶¶

(C) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination. ¶¶

(b) An event in which equipment is disabled or fails to function as designed when: ¶¶

(A) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;¶¶

(B) The equipment is required to be available and operable when it is disabled or fails to function; and¶¶

(C) No redundant equipment is available and operable to perform the required safety function.¶¶

(c) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.¶¶

(d) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:¶¶

(A) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of Secs. 20.1001-20.2401 of 10 CFR part 20 for the material; and¶¶

(B) The damage affects the integrity of the licensed material or its container.¶¶

(3) Preparation and submission of reports. Reports made by licensees in response to the requirements of this rule must be made as follows:¶¶

(a) Licensees must make reports required by sections (1) and (2) of this rule by telephone to the Authority. To the extent that the information is available at the time of notification, the information provided in these reports must include:¶¶

NOTE: The 24-hour telephone number for the Authority is 971-673-0490 1-800-452-0311.¶¶

(A) The caller's name and call back telephone number;¶¶

(B) A description of the event, including date and time;¶¶

(C) The exact location of the event;¶¶

(D) The isotopes, quantities, and chemical and physical form of the licensed material involved; and¶¶

(E) Any personnel radiation exposure data available.¶¶

(b) Written report. Each licensee who makes a report required by sections (1) or (2) of this rule must submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be ~~faxed or sent to the Department~~ mailed to the Authority with Attention to Manager, Radiation Protection Services, Center for Health Protection, 800 NE Oregon Street, Suite 640, Portland, OR 97232. The reports must include the following:¶¶

(A) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;¶¶

(B) The exact location of the event;¶¶

(C) The isotopes, quantities, and chemical and physical form of the licensed material involved;¶¶

(D) Date and time of the event;¶¶

(E) Corrective actions taken or planned and the results of any evaluations or assessments; and¶¶

(F) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.¶¶

(4) The provisions of this rule apply to licensees subject to the notification requirements in OAR 333-102-0200(5).

Statutory/Other Authority: ORS 453.635, 453.665

Statutes/Other Implemented: ORS 453.605 - 453.807

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-105-0560 (Industrial Radiographic Operators) is amended to be compatible with 10 CFR Parts 47 and 34.83 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. The rule amendment also requires when the dosimeter reads greater than two millisieverts and the possibility of radiation exposure cannot be ruled out as the cause, the individual's dosimeter must be sent for processing within 24 hours. Pocket dosimeters found to be off-scale and personnel dosimeter that do not require processing, evaluation of the dosimeter must be started within 24 hours.

CHANGES TO RULE:

333-105-0560

Radiation Safety Requirements: Personnel Monitoring ¶¶

(1) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.¶¶

(a) Pocket dosimeters must have a range from zero to two millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.¶¶

(b) Each personnel dosimeter must be assigned to and worn by only one individual.¶¶

(c) Film badges must be exchanged and processed at periods not to exceed one month and other personnel dosimeters ~~processed and evaluated by an accredited NVLAP processor~~ must be replaced at periods not to exceed three months.¶¶

~~(d) After replacement, each All personnel dosimeters must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each personnel dosimeter in 14 calendar days, such circumstances must be documented and available for review by the Authority evaluated at least quarterly or promptly after replacement, whichever is more frequent.~~¶¶

(2) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with OAR 333-105-0700.¶¶

(3) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with OAR 333-105-0700(1). Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.¶¶

(4) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than two millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with OAR 333-105-0700.¶¶

(5) If a personnel dosimeter is lost or damaged, the worker must cease work immediately until a replacement personnel dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with OAR 333-105-0700.¶¶

(6) Dosimetry reports ~~received from the accredited NVLAP personnel dosimeter processor~~ must be retained in accordance with OAR 333-105-0700.¶¶

(7) Each alarming ratemeter must:¶¶

(a) Be checked to ensure that the alarm functions properly before using at the start of each shift;¶¶

- (b) Be set to give an alarm signal at a preset dose rate of five millisieverts (500 mrem per hour) with an accuracy of plus or minus 20 percent of the true radiation dose rate;¶
- (c) Require special means to change the preset alarm function; and¶
- (d) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee must maintain records of alarming ratemeter calibrations in accordance with OAR 333-105-0700(2).

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-105-0700

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-105-0700 (Industrial Radiographic Operators) is amended by replacing the terms film badge and TLD processor to personnel dosimeter throughout the rule.

CHANGES TO RULE:

333-105-0700

Recordkeeping Requirements: Records of Personnel Monitoring ¶¶

Each licensee must maintain the following exposure records specified in OAR 333-105-0560:¶¶

(1) Direct reading dosimeter readings and yearly operability checks required by OAR 333-105-0560(2) and 333-105-0560(3) for three years after the record is made;¶¶

(2) Records of alarming ratemeter calibrations for three years after the record is made;¶¶

(3) ~~Reports received from the film badge or TLD processor~~ Personnel dosimeter results until the Authority terminates the license or registration; and¶¶

(4) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, ~~or lost or damaged film badges or TLD's~~, personnel dosimeters until the Authority terminates the license or registration.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-105-0740

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-105-0740 is amended to be compatible with 10 CFR Part 34.101 by inserting Radiation Protections Services' address to report activities performed that are not listed within the licensee's radioactive material license.

CHANGES TO RULE:

333-105-0740
Notifications ¶

(1) In addition to the reporting requirements specified in 10 CFR 30.50 and in ~~division 120 of these rules~~ OAR chapter 333, division 120, each licensee must provide a written report to the Authority within 30 days of the occurrence of any of the following incidents involving radiographic equipment: ¶

(a) Unintentional disconnection of the source assembly from the control cable; ¶

(b) Inability to retract the source assembly to its fully shielded position and secure it in this position; ¶

(c) Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or ¶

(d) An indicator on a radiation machine fails to show that radiation is being produced. ¶

(2) The licensee must include the following information in each report submitted under section (1) of this rule, and in each report of overexposure submitted under OAR 333-120-0720 which involves failure of safety components of radiography equipment: ¶

(a) Description of the equipment problem; ¶

(b) Cause of each incident, if known; ¶

(c) Name of the manufacturer and model number of equipment involved in the incident; ¶

(d) Place, date, and time of the incident; ¶

(e) Actions taken to establish normal operations; ¶

(f) Corrective actions taken or planned to prevent recurrence; and ¶

(g) Names and qualifications of personnel involved in the incident. ¶

(3) Any licensee conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, must notify the Authority at Radiation Protection Services, 800 NE Oregon St. Suite 640, Portland, Oregon 97232 prior to exceeding the 180 days.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-113-0210

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-113-0210 (Well Logging Operators) is amended to be compatible with 10 CFR Part 39.65 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.

CHANGES TO RULE:

333-113-0210

Requirements for Personnel Safety: Personnel Monitoring ¶¶

(1) The licensee must not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of licensed radioactive materials, ~~a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter must be promptly processed.¶¶

(2) The licensee must provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.¶¶

(3) Personnel monitoring records must be maintained in accordance with OAR 333-100-0057 and for inspection until the Authority authorizes disposition.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-0680

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-116-0680 is amended to be compatible with 10 CFR Part 35.3910 by changing the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

CHANGES TO RULE:

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 U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph (2)(b)(F) of this rule. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses License Toolkit webpage at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>. 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 (2)(b)(E) of this rule. 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~~Council on Post-~~Graduatedoctoral~~ 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 333-116-0680, 333-116-0740, or U.S. Nuclear Regulatory Commission 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 subparagraphs (2)(b)(F)(i) through (iii) within this rule. Radiopharmaceuticals containing radionuclides not listed in subparagraphs (2)(b)(F)(i) through (iii) are regulated under OAR 333-116-0485. This work experience must involve a minimum of three cases in subparagraphs (2)(b)(F)(i) through (iii) within this rule 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;¶¶

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 photon energy of less than 150 keV, for which a written directive is required; and¶
(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in section (2) 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:-¶
(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¶
(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, 333-116-0740, 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 subsections (2)(a) and (2)(b) of this rule.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-0690

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-116-0690 is amended to be compatible with 10 CFR Part 35.490 by changing the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

CHANGES TO RULE:

333-116-0690

Training for Use of Manual 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 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. 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~~Council on Post-~~Graduate~~doctoral 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 OAR 333-116-0690, 333-116-0740 or equivalent U.S. Nuclear Regulatory or Agreement State requirements at a medical facility authorized to use byproduct materials under OAR 333-116-0420. 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 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~~Council 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 that the individual has satisfactorily completed the requirements in subsections(2)(a), (2)(b) and (2)(c) of this rule and is able to independently fulfill the radiation safety related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 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 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.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-0720

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-116-0720 is amended to be compatible with 10 CFR Part 35.690 by changing the title of an eligible training program from the Committee on Post Graduate Training of the American Osteopathic Association to Council on Postdoctoral Training of the American Osteopathic Association.

CHANGES TO RULE:

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 U.S. 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 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) 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~~council on ~~Post-Graduate~~Postdoctoral 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 that is authorized to use byproduct materials in OAR 333-116-0480 involving:¶

(i) Reviewing full calibration measurements and periodic spotchecks;¶

(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 U.S. 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~~council 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 (2)(a) and (2)(b), and section (3) of this rule, and is able to independently fulfill the radiation safety related duties 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 obtained from either:-¶

(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 subsections (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

RULE SUMMARY: OAR 333-116-1000 (Radionuclides in the Healing Arts) is amended to be compatible with 10 CFR Part 35.3045 by removing the word "and" and inserting "or" at the end of paragraph (1)(a)(A). In addition, inserted rule language will direct the licensee reporting a medical event to identify the individual who was subject with the event, be identified by their Social Security number or an identification number issued by the licensee.

CHANGES TO RULE:

333-116-1000

Report and Notification of a Medical Event ¶¶

(1) A licensee must report any medical event as defined in OAR 333-116-0020, 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:¶¶

(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.¶¶

(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 ~~the~~ ~~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.¶

(6) A licensee shall:¶

(a) Maintain a copy of the report described in section (3) of this rule and annotate as follows:¶

(A) Name of the individual who is the subject of the event; and¶

(B) Identification number, or if no other identification number is available, the Social Security number of the individual who is the subject of the event.¶

(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-1015

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-116-1015 (Fetus Medical or Breast-Feeding Event) is amended to be compatible with 10 CFR Part 35.3047 by adding rule language to direct the licensee reporting a medical event to identify the individual who was subject with the event, be identified by their Social Security number or an identification number issued by the licensee.

CHANGES TO RULE:

333-116-1015

~~Specific Requirements for Positron Emission Tomography (PET) Facilities: Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child~~ ¶

- (1) A licensee must report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.¶
- (2) A licensee must report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual who:¶
- (a) Is greater than 50 mSv (5 rem) total effective dose equivalent; or¶
- (b) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.¶
- (3) The licensee must notify the Authority by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.¶
- (4) The licensee must submit a written report to the Authority within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in sections (1) or (2) of this rule.¶
- (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 embryo/fetus or the nursing child;¶
- (F) What actions, if any, have been taken or are planned to prevent recurrence; and¶
- (G) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.¶
- (b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.¶
- (5) The licensee must provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under sections (1) or (2) of this rule, unless the referring physician personally informs the licensee either that ~~the or she~~ they will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this rule, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee must inform the mother, or the mother's or child's 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.¶
- (6) A licensee shall:¶
- (a) Maintain in its own records a copy of the report described in section (4) and annotate as follows:¶
- (A) Name of the individual who is the subject of the event; and¶
- (B) Identification number or if no other identification number is available, the Social Security number of the individual who is the subject of the event.¶
- (b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-118-0070

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-118-0070 is amended to be compatible with 10 CFR Part 71.17 by changing the recipient's name to U.S. Nuclear Regulatory Commission (NRC), Document Control Desk Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards when notifying the NRC when using a transportation package for the first time.

CHANGES TO RULE:

333-118-0070

General License: Nuclear Regulatory Commission-Approved Packages ¶¶

- (1) A general license is hereby issued to any licensee of the Authority to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the U.S. Nuclear Regulatory Commission. ¶¶
- (2) This general license applies only to a licensee who has a quality assurance program approved by the Authority as satisfying the provisions of 10 CFR Part 71, subpart H and any applicable requirements in OAR 333-118-0200.¶¶
- (3) Each licensee issued a general license under section (1) of this rule shall:¶¶
 - (a) Maintain a copy of the Certificate of Compliance, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;¶¶
 - (b) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of 10 CFR Parts 71, subparts A, G, and H; and¶¶
 - (c) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of ~~Spent Fuel Storage and Transportation~~ Fuel Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, using an appropriate method listed in 10 CFR Parts 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.¶¶
- (4) This general license applies only when the package approval authorizes use of the package under this general license.¶¶
- (5) For a Type B or fissile material package, the design of which was approved by the U.S. Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR Parts 71.19.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0450

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-120-0450 is amended to be compatible with 10 CFR Part 20.1906 by adding the Authority's notification telephone number 1-800-452-0311 when removable radioactive surface contamination exceeds the regulatory limits.

CHANGES TO RULE:

333-120-0450

Precautionary Procedures: Procedures for Receiving and Opening Packages ¶¶

(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 49 CFR 173.435 Table of A1 and A2 Values for Radionuclides, must make arrangements to receive:¶¶

(a) The package when the carrier offers it for delivery; or¶¶

(b) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.¶¶

(2) Each licensee must:¶¶

(a) Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in OAR 333-118-0020;¶¶

(b) Monitor the external surfaces of a labeled package for radiation levels; and¶¶

NOTE: Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.¶¶

(c) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.¶¶

(3) The licensee must perform the monitoring required by section (2) of this rule as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.¶¶

(4) The licensee must immediately notify the final delivery carrier and the Authority, by telephone at 1-800-452-0311 when:¶¶

(a) Removable radioactive surface contamination exceeds the limits of OAR 333-118-0150(9);¶¶

(b) External radiation levels exceed the limits of OAR 333-118-0150(9)(a).¶¶

(5) Each licensee must:¶¶

(a) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and¶¶

(b) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.¶¶

(6) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of section (2) of this rule, but are not exempt from the survey requirement in section (2) of this rule for measuring radiation levels, which is required to ensure that the source is still properly lodged in its shield.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0700

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-120-0700 is amended to be compatible with 10 CFR Part 20.2201 by adding additional language of licensees having an installed Emergency Notification System to make reports to the NRC Commission Operations Center in accordance with 10 CFR, Part 50.72 and all other licensees shall make reports by telephone to the Authority at 1-800-452-0311.

CHANGES TO RULE:

333-120-0700

Reports of Theft or Loss of Licensed Material ¶

(1) Telephone reports: Each licensee or registrant must report by telephone to the Authority as follows:¶

(a) Immediately after its occurrence becomes known to the licensee or registrant, any lost, stolen, or missing licensed or registered device, or licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 10 CFR Part 20 Appendix C ~~to 20.1001 to 20.2401~~, under such circumstances that it appears to the licensee or registrant that an exposure could result to persons in unrestricted areas; or¶

(b) Within 30 days after the occurrence of any lost, stolen, or missing licensed or registered device, or licensed radioactive material, becomes known to the licensee or registrant, all licensed or registered material in a quantity greater than ten times the quantity specified in 10 CFR Part 20 Appendix C ~~to 20.1001 to 20.2401~~ that is still missing at this time.¶

(2) Reports required in section (1) of this rule must be made as follows:¶

(a) Licensees having an installed Emergency Notification System shall make the reports to the U.S. Nuclear Commission Operations Center in accordance with 10 CFR, Part 50.72; and¶

(b) All other licensees shall make reports by telephone to the Authority at 1-800-452-0311.¶

~~(23)~~ Written Reports: Each licensee or registrant required to make a report under section (1) of this rule must make a written report to the Authority, within 30 days after making the telephone report, setting forth the following information:¶

(a) A description of the device or licensed material involved, including kind, quantity, and chemical and physical form; and¶

(b) A description of the circumstances under which the loss or theft occurred; and¶

(c) A statement of disposition, or probable disposition, of the device or licensed material involved; and¶

(d) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and¶

(e) Actions that have been taken, or will be taken, to recover the material; and¶

(f) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of a device or licensed material; and¶

(g) Subsequent to filing the written report, the licensee must also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.¶

~~(34)~~ The licensee must prepare any report filed with the Authority pursuant to this rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0710

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-120-0710 is amended to be compatible with 10 CFR Part 20.2202 by adding additional language of licensees having an installed Emergency Notification System to make reports required by sections (1) and (2) of this rule to the NRC Operations Center in accordance with 10 CFR 50.72; and reports made by other licensees or registrants must be made by telephone to the Authority at 1-800-452-0311

CHANGES TO RULE:

333-120-0710

Reports: Notification of Incidents ¶¶

(1) Immediate notification: Notwithstanding any other requirements for notification, each licensee, or registrant, must immediately report any event involving a device or licensed radioactive material possessed by the licensee, or registrant, which may have caused or threatens to cause any of the following conditions:¶¶

(a) An individual to receive:¶¶

(A) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or¶¶

(B) A lens dose equivalent of 0.75 Sv (75 rem) or more; or¶¶

(C) A shallow-dose equivalent to the skin or extremities of 2.5 gray (250 rad) or more; or¶¶

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).¶¶

(2) Twenty-four hour notification: Each licensee or registrant must, within 24 hours of discovery of the event, report any event involving loss of control of a device or licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:¶¶

(a) An individual to receive in a period of 24 hours:¶¶

(A) A total effective dose equivalent exceeding 0.05 Sv (5 rems); or¶¶

(B) A lens dose equivalent exceeding 0.15 Sv (15 rems); or¶¶

(C) A shallow-dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rems); or¶¶

(b) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this rule do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).¶¶

(3) The licensee must prepare any report filed with the Authority pursuant to this rule so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.¶¶

(4) Reports made by licensees, ~~or registrants~~, in response to the requirements of ~~sub~~this rule must be made as follows:¶¶

(a) Licensees having an installed Emergency Notification System shall make the reports required by sections (1)(a) and (b)(2) of this rule must be made by telephone and either by telegram, e~~l~~to the NRC Operations Center in accordance with 10 CFR 50.72; and¶¶

(b) Reports made by licensees, or registrants, in response to the requirements of sectrionic mail, or facsimile to the Authority, s (1) and (2) of this rule must be made by telephone to the Authority at 1-800-452-0311. ¶¶

(5) The provisions of this rule do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under OAR 333-120-0730.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-121-0320

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-121-0320 (Irradiator Operators) is amended to be compatible with 10 CFR Part 36.55 by removing the requirement that a personnel dosimeter must be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program processor. In addition, within the rule, the licensee will now be required to evaluate personnel dosimeters at least quarterly or promptly after replacement, whichever is more frequent.

CHANGES TO RULE:

333-121-0320

Personnel Monitoring ¶

(1) Irradiator operators must wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be ~~accredited by the National Voluntary Laboratory Accreditation Program for~~ capable of detecting high energy photons in the normal and accident dose ranges, see OAR 333-120-0200(3). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be ~~process~~ replaced at least monthly, and all other personnel dosimeters must be processed at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. ¶

(2) Other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ±20% percent of the true radiation dose.

Statutory/Other Authority: ORS 453.605 - 453.807

Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-125-0025

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-125-0025 (Materials Safety and Security) is amended to be compatible with 10 CFR Part 37.23 by adding the statement "the licensee shall provide the oath or affirmation certifications to the Authority, attention: Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland, Oregon 97232" within this rule.

CHANGES TO RULE:

333-125-0025

Background Investigations and Access Control Program: Access Authorization Program Requirements ¶

(1) Granting unescorted access authorization. Licensees shall implement the following requirements under OAR 333-125-0020 through 333-125-0095 for granting initial or reinstated unescorted access authorization: ¶

(a) Individuals who have been determined to be trustworthy and reliable, shall complete the security training required by OAR 333-125-0115 before being allowed unescorted access to category 1 or category 2 of radioactive material. ¶

(b) Reviewing officials shall be the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 of radioactive material possessed by the licensee. ¶

(c) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The licensee shall provide the oath or affirmation certifications to the Authority, attention: Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland, Oregon 97232. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with OAR 333-125-0070. ¶

(2) Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive materials and access to the licensee's safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling. ¶

(3) Reviewing officials cannot approve other individuals to act as reviewing officials. ¶

(4) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if: ¶

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or ¶

(b) The individual is subject to a category listed in OAR 333-125-0085.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.635

AMEND: 333-125-0080

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-125-0080 is amended to be compatible with 10 CFR Part 37.27 by revising the addresses that fingerprint cards must be mailed to for processing and the email address used to obtain additional fingerprint cards. The address to submit fingerprint cards to is U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, Attn: Criminal History Program/Mail Stop – T-07D04M, Maryland 20852. To request additional fingerprint cards, the email address is MAILSVS.Resource@nrc.gov.

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, 11545 Rockville Pike, 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 FORM at MAILSVS.Resource@nrc.gov.~~ Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/site-help/e-submittalsecurity/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 ~~Security Branch, Division of Facilities and Security at 301-415-7513~~ 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 Electronic Submittals Licensee Criminal History Records Checks & Firearms Background Check information page at <https://www.nrc.gov/site-help/e-submittalsecurity/chp.html> and see the link for the Criminal History Program under Electronic Submission Systems.) "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

AMEND: 333-125-0120

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-125-0120 (Protection of Information) is amended to be compatible with 10 CFR Part 37.43 by inserting the statement "implementation procedures, or the list of individuals that have been approved for unescorted access" throughout this rule.

CHANGES TO RULE:

333-125-0120

Physical Protection Requirements During Use: Security Program, Protection of Information ¶

(1) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall secure from public disclosure and limit access to their security plan and implementation procedures, and the list of individuals that have been approved for unescorted access. ¶

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of the security ~~plan~~ and implementation plan ~~procedures, and the list of individuals that have been approved for unescorted access.~~ ¶

(3) Before granting an individual access to the security ~~plan~~, implementation plan ~~procedures, or the list of individuals that have been approved for unescorted access,~~ the licensee shall: ¶

(a) Evaluate an individual's need to know of the security ~~plan~~, implementation plan ~~procedures, or the list of individuals that have been approved for unescorted access;~~ and ¶

(b) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in OAR 333-125-0060(2)(b) through (2)(e)(B). ¶

(4) Licensees need not subject the following individuals to the background investigation elements for protection of information: ¶

(a) The categories of individuals listed in OAR 333-125-0085(1)(a) through (m); or ¶

(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in OAR 333-125-0060(2)(b) through (2)(e)(B) has been provided by the security service provider. ¶

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and allowed access to the security ~~plan~~, implementation plan, ~~procedures, or the list of individuals that have been approved for unescorted access.~~ ¶

(6) Licensees shall maintain a list of persons currently approved for access to the security ~~and~~, implementation plan ~~procedures, or the list of individuals that have been approved for unescorted access.~~ When a licensee determines that a person no longer needs access to the security ~~plan~~, implementation plan ~~procedures, or the list of individuals that have been approved for unescorted access,~~ or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security ~~plan~~, implementation procedures, ~~or the list of individuals that have been approved for unescorted access.~~ ¶

(7) When not in use, the licensee shall store its security ~~plan~~, implementation plan ~~procedures, and the list of individuals that have been approved for unescorted access~~ in a manner to prevent unauthorized access. Information stored in non-removable electronic form must be password protected. ¶

(8) The licensee shall retain as a record for three years after the document is no longer needed: ¶

(a) A copy of the information protection procedures; and ¶

(b) The list of individuals approved for access to the security ~~plan~~, implementing procedures, ~~and the list of individuals approved for access to the security plan.~~

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.635

AMEND: 333-125-0125

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-125-0125 (Local Law Enforcement) is amended to be compatible with 10 CFR Part 37.45 by requiring the licensee to report in writing and submitted to Radiation Protection Services when coordination cannot be obtained with the local law enforcement agency regarding responds to threats at the licensee's facility.

CHANGES TO RULE:

333-125-0125

Physical Protection Requirements During Use: Local Law Enforcement Agency (LLEA) Coordination-~~(LLEA)~~ ¶

(1) A licensee subject to OAR 333-125-0100 through 333-125-0155 shall coordinate, to the extent practicable, with a LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:¶

(a) A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with OAR 333-125-0100 through 333-125-0155; and¶

(b) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.¶

(2) The licensee shall notify the Authority ~~and the NRC regional office at U.S. Nuclear Regulatory Commission, Region IV, Division of Nuclear Materials Safety, 1600 E. Lamar Blvd., Arlington, TX 76011-4511; where electronic mail is appropriate, it shall be addressed to RidsRgn4MailCenter.Resource@nrc.gov~~ in writing by mail to Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland, Oregon 97232 within three business days if:¶

(a) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or¶

(b) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.¶

(3) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three years.¶

(4) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

Statutory/Other Authority: ORS 453.635

Statutes/Other Implemented: ORS 453.635

AMEND: 333-125-0180

NOTICE FILED DATE: 11/29/2022

RULE SUMMARY: OAR 333-125-0180 (Advance Notification) is amended to be compatible with 10 CFR Part 37.77 by requiring the licensee to notify the Authority in writing when category one materials are being transported through the State of Oregon.

CHANGES TO RULE:

333-125-0180

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. Notifications to the Authority must be mailed to Radiation Protection Services, 800 NE Oregon Street, Suite 640, Portland, Oregon 97232. ¶

(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 Materials Safety, ~~State, Tribal, and Rulemaking~~ security, State and Tribal 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 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. ¶

(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