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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
06/28/2018 11:02 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Federal Compatibility, Dosimetry, and Positron Emission Tomography Training Requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/23/2018 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S):

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to amend Oregon Administrative Rules (OAR) relating to the X-ray and radioactive material programs within the Radiation Protection Services (RPS) section.

The radioactive materials licensing (RML) program is proposing to amend rules for miscellaneous corrections with the Nuclear Regulatory Commission's (NRC) regulations 10 CFR parts 20, 30, 37, 40, 70, 71, within OAR divisions 100, 102, 116, 118, 120, and 125.

Amended rules in division 120 are being proposed to discontinue the requirement for monitoring of exposures while medical staff are using fluoroscopic equipment if the registrant can demonstrate, that the worker is not being exposed to more than 10% of the exposure limits specified in OAR 333-120-0100.

Proposed amendments in division 116 will discontinue the requirement of an Authorized User to complete an additional 40 hours of Positron Emission Tomography (PET) training course.

A proposed rule amendment in division 124 (Civil Penalties) will not require a person to receive a Notice of Violation prior to being issued a civil penalty for violating OAR 333-101-0005, OAR 333-101-0020, OAR 333-101-0045, OAR 333-102-0001, OAR 333-119-0020, or any violation within OAR chapter 333, division 103.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Nuclear Regulatory Commission:
10 CFR Parts 20 through 71
http://www.nrc.gov/reading-rm/doc-collections/cfr/

FISCAL AND ECONOMIC IMPACT:

RPS does not anticipate any impacts to licensees by amending OARs for federal compatibility since the NRC's rules currently supersede OARs pertaining to the licensing and transportation of radioactive materials. Amended rules within divisions 116 and 120 could reduce the burden of registrants having to monitor occupational exposures during fluoroscopic operations and the additional 40-hour training program required for PET operations

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no additional cost of compliance to state agencies, units of local government, or the public because of these proposed rule amendments.

(2)(a) RPS does not possess the data to determine how many small businesses providing X-ray and radioactive materials services will be subject to these rules. It is not anticipated that small businesses will be negatively impacted by these proposed amended rules.

(b) X-ray registrants who discontinue occupational exposure monitoring for workers using fluoroscopic equipment will need to provide the Authority documentation that occupational exposures do not exceed 10% of the exposure limits in OAR 333-120-0100.

(c) No additional supplies, labor or administrative oversight will be required for compliance with the proposed rules.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the proposed rulemaking. Proposed rules being amended are based on federal regulation requirements and existing licensing and registration requirements. No impacts are anticipated.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
333-100-0080, 333-102-0115, 333-102-0200, 333-102-0305, 333-102-0310, 333-116-0880, 333-118-0020, 333-118-0070, 333-120-0200, 333-120-0210, 333-120-0320, 333-124-0010, 333-125-0080, 333-125-0180

AMEND: 333-100-0080

RULE SUMMARY: OAR 333-100-0080, Deliberate Misconduct. To be compatible with 10 CFR Part 40.10; insert the

term "applicant" within the rule.

CHANGES TO RULE:

333-100-0080
Deliberate Misconduct ¶

(1) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor, of any licensee, or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this rule; may not: ¶
(a) Engage in deliberate misconduct that causes or, but for detection, would have caused, a licensee or applicant to be in violation of any rule, regulation, or order, or any term, condition, or limitation of any license, issued by the Authority; or ¶
(b) Deliberately submit to the Authority, a licensee, ~~or a licensee~~an applicant or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Authority. ¶
(2) A person who violates subsection (1)(a) or (1)(b) of this rule may be subject to enforcement action in accordance with OAR 333-100-0035. For purposes of subsection (1)(a) of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows: ¶
(a) Would cause a licensee or applicant to be in violation of any rule, regulation, or order, or any term, condition, or limitation, of any license issued by the Authority; or ¶
(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, contractor, or subcontractor.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.625 - 453.807

AMEND: 333-102-0115

RULE SUMMARY: OAR 333-102-0115, General Licenses – Radioactive Material Other than Source Material: Certain Measuring Gauging and Controlling Devices. Correct the conversion of “37 MBq (1mCi)” to 37 MBq (10 mCi)”.

CHANGES TO RULE:

333-102-0115
General Licenses - Radioactive Material Other than Source Material: Certain Measuring, Gauging and Controlling Devices ¶

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of OAR 333-103-0015 and sections (2), (3) and (4) of this rule, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.¶
(2) The general license in section (1) of this rule applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the Authority pursuant to OAR 333-102-0200 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, that authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.¶
(3) The devices must have been received from one of the specific licensees described in section (2) of this rule or through a transfer made in accordance with subsection (4)(i) of this rule.¶
NOTE: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.¶
(4) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in section (1) of this rule:¶
(a) Must assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and must comply with all instructions and precautions provided by such labels;¶
(b) Must assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:¶
(A) Devices containing only krypton need not be tested for leakage of radioactive material; and¶
(B) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or gamma emitting material or 10 microcuries (0.37 MBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.¶
(c) Must assure that tests required in subsection (4)(b) of this rule and other testing, installation servicing and removing from installation involving the radioactive materials, its shielding or containment, are performed:¶
(A) In accordance with the instructions provided by the labels; or¶
(B) By a person holding an applicable specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities.¶
(d) Must maintain records showing compliance with the requirements of subsections (4)(b) and (4)(c) of this rule. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment. The licensee must retain these records as follows:¶
(A) Records of tests for leakage of radioactive material required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.¶

(B) Records of tests of the on-off mechanism and indicator required by subsection (4)(b) of this rule must be maintained as required in OAR 333-100-0057.¶
(C) Records which are required by subsection (4)(c) of this rule must be maintained as required in OAR 333-100-0057.¶
(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee must immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Authority. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be submitted to the Authority within 30 days. Under these circumstances, the criteria set out in OAR 333-120-0190, as determined by the Authority, on a case-by-case basis;¶
(f) Must not abandon the device containing radioactive material;¶
(g) Except as provided in subsection (4)(i) of this rule, must transfer or dispose of the device containing radioactive material only by export as provided by subsection (4)(l) of this rule, by transfer to another general licensee as authorized in subsection (4)(i) of this rule, or by transfer to a specific licensee of the Authority, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes the individual to receive the device; and¶
(A) Must furnish to the Authority, within 30 days after transfer of a device to a specific licensee or export, a report containing identification of the device by manufacturer's name, model number, serial number, the date of transfer, and the name, address and license number of the person receiving the device;¶
(B) The general licensee must obtain written Authority approval before transferring the device to any other specific licensee not specifically identified in subsection (4)(g) of this rule.¶
(h) A holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:¶
(A) Verifies that the specific license authorized the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;¶
(B) Removes, alters, covers, or clearly and unambiguously augments the existing label so that the device is labeled in compliance with OAR 333-120-0430, however the manufacturer model and serial numbers must be retained;¶
(C) Obtains manufacturer's or initial transferor's information concerning maintenance that are applicable under the specific license (such as leak testing procedures); and¶
(D) Reports the transfer under OAR 333-102-0115(4)(g)(A).¶
(i) Must transfer the device to another general licensee only:¶
(A) Where the device remains in use at a particular location. In such case the transferor must give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Authority the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the date of transfer, the name and address of the transferee and the location of use, and the name, title and phone number of the individual who is a point of contact between the Authority and the transferee. This individual must have the knowledge and authority to take actions to ensure compliance with the appropriate rules and requirements concerning the possession and use of these devices; or¶
(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.¶
(j) Must comply with the provisions of OAR 333-120-0700 and 333-120-0710 for reporting radiation incidents, theft or loss of licensed material but shall be exempt from the other requirements of divisions 111 and 120 of this

chapter;¶
(k) Must submit the required Authority form and receive from the Authority a validated registration certificate acknowledging the general license and verifying that all provisions of these rules have been met. The form must be submitted within 30 days after the first receipt or acquisition of such device. The general licensee must develop and maintain procedures designed to establish physical control over the device as described in this rule and designed to prevent transfer of such devices in any form, including metal scrap, to persons not authorized to receive the devices.¶
(l) Shall not export a device containing radioactive material except in accordance with 10 CFR Part 110.¶
(5) The general license in section (1) of this rule does not authorize the manufacture of devices containing radioactive material.¶
(6) The general license provided in section (1) of this rule is subject to the provisions of OAR 333-100-0040 through 333-100-0055, 333-102-0335, 333-103-0015 and 333-118-0050.¶
(7) The general licensee possessing or using devices licensed under the general license established by section (1) of this rule must report in writing to the Authority any changes in information furnished by the licensee on the required Authority form. The report must be submitted within 30 days after the effective date of such change.¶
(8) The licensee must appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, must ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.¶
(9)(a) A device distributed or otherwise received as a generally licensed device must be registered with the Authority. Each address for a location of use, as described under subsection (9)(b) of this rule, represents a separate general licensee and requires a separate registration and fee. Devices containing more than 37 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, any quantity of americium-241, 3.7 MBq (0.1 mCi) of radium 226 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label are required to have a specific license.¶
(b) In registering devices, the general licensee must furnish the following information and any other information specifically requested by the Authority:¶
(A) Name and mailing address of the general licensee;¶
(B) Information about each device. The manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label);¶
(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under section (8) of this rule.¶
(D) Address or location at which the device(s) are used and stored. For portable devices, the address of the primary place of storage.¶
(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.¶
(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.¶
(10) General licensees must report changes to their mailing address or the location of use (including a change in name of general licensee) to the Authority within 30 days of the effective date of the change.¶
(11) Generally licensed devices that are not in use for longer than two years must be transferred to an authorized recipient or disposed of as radioactive waste. Shutters must be locked in the closed position on devices that are not being used or are in storage. The testing required by subsection (4)(b) of this rule need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.¶
(12) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in section (9) of this rule are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction

for a period less than 180 consecutive days in any calendar year. The Nuclear Regulatory Commission does not require registration information from such licensees.¶
(13) The general license in section (1) of this rule does not authorize the manufacture or import of devices containing radioactive material.¶
~~[Publications: Publications referenced are available from the agency.]~~
Statutory/Other Authority: ORS 453.635, 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-102-0200

RULE SUMMARY: OAR 333-102-0200, General Licenses — Radioactive Material Other than Source Material: General Requirements for the Issuance of Specific Licenses . To be compatible with 10 CFR Parts 30.35, 40.36, and 70.25; remove the term “following” and insert the term “meeting”.

CHANGES TO RULE:

333-102-0200
General Licenses - Radioactive Material Other than Source Material: General Requirements for the Issuance of Specific Licenses ¶

An application for a specific license, will be approved if:¶
(1) The application is for a purpose authorized by the Act;¶
(2) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;¶
(3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;¶
(4) The applicant satisfies any applicable special requirements contained in divisions 102, 105, 113, 115, 116, 117, or 121 of this chapter; and¶
(5) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Authority determines will significantly affect the quality of the environment, the Authority Manager or designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of 10 CFR, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion must be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this rule, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that can adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values. Upon a determination that an application meets the requirements of the Act, and the rules of the Authority, the Authority will issue a specific license authorizing the possession and use of radioactive material ("Radioactive Materials License").¶
(6) Financial assurance and recordkeeping for decommissioning ~~follow~~meeting the specific requirements listed below:¶
(a) 10 CFR 30.35 and 30.36 for radioactive material that is not source or special nuclear material; or¶
(b) 10 CFR 40.36 for source material; or¶
(c) 10 CFR 70.25 for special nuclear material.¶
~~[Publications: Publications referenced are available from the agency.]~~
Statutory/Other Authority: ORS 453.635, 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-102-0305

RULE SUMMARY: OAR 333-102-0305, Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Specific Terms and Conditions of License . To be compatible with Atomic Energy Act of 1954 as amended and 10 CFR Parts 40.46 and 70.36; add to 10 CFR Parts, sections 40.46 and 70.36; remove the term “Atomic Energy Act” and insert “Authority”. Remove the term “promote the common defense and security”, and remove 10 CFR 30.35.

CHANGES TO RULE:

333-102-0305
Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Specific Terms and Conditions of License ¶

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority. ¶
(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing. ¶
(3) An application for transfer of license must include: ¶
(a) The identity, technical and financial qualification of the proposed transferee; and ¶
(b) Financial assurance for decommissioning as required by 10 CFR Parts 30.35~~ or 4~~, 40.36, 40.46, and 70.36. ¶
(4) Each person licensed by the Authority pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, use and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter. ¶
(5) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth ~~in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, as amended~~by the Authority, whether or not these provisions are expressly set forth in the license. ¶
(6) The Authority may incorporate, in any license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to: ¶
(a) ~~Promote the common defense and security; ¶~~
~~(b)~~ Protect health or to minimize danger to life or property; ¶
(~~c~~b) Protect restricted data; and ¶
(~~d~~c) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder. ¶
(7) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Authority. The licensee may change the approved plan without Authority approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Authority and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Authority. ¶
(8) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m

generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85, respectively, in accordance with OAR 333-116-0330. The licensee must record the results of each test and retain each record for three years after the record is made. ¶
(9)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Authority in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against: ¶
(A) The licensee; ¶
(B) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or ¶
(C) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee. ¶
(b) This notification must indicate: ¶
(A) The bankruptcy court in which the petition for bankruptcy was filed; and ¶
(B) The date of the filing of the petition. ¶
(10) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee. ¶
(11) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State. ¶
(12) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210. ¶
(13) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by this section must be kept until inspection by the Authority. ¶
(14) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material." ¶
(15) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by this section must be kept until inspection by the Authority. ¶
(16) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources. ¶
(17) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer ¶
(18) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the Authority, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection Services section. ¶
(19) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report. ¶
(20) Testing for leakage or contamination of sealed sources must be in accordance with requirements in OAR 333-

120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested. ¶
(21) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180. ¶
(22) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260. ¶
(23) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license. ¶
(24) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with OAR 333-116-0290. ¶
(25) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee. ¶
(26) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device. ¶
(27) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement. ¶
(28) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than n+1 where n=the number of cameras. ¶
(29) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of two independent physical controls that form two separate tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee. ¶
(30) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs. ¶
(31) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall: ¶
(a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium. ¶
(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-102-0285(3). ¶
(32) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be: ¶

(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; or ¶
(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100. ¶
(33) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of OAR 333-116-0910.
Statutory/Other Authority: ORS 453.635, 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-102-0310

RULE SUMMARY: OAR 333-102-0310, Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas . To be compatible with 10 CFR Parts 20.1404 and 20.1406; insert the term “A description to the extent practical, how operations will be conducted to minimize the introduction of residual radioactivity into the site including the subsurface”. In addition, insert the term “in the form of a trust fund”.

CHANGES TO RULE:

333-102-0310
Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas ¶

(1)(a) Except as provided in subsection (1)(b) of this rule, each specific license must expire at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under OAR 333-102-0315 before the expiration date stated in the existing license (or, for those licenses subject to subsection (1)(b) of this rule, before the deemed expiration date in that section). If an application for renewal has been filed before the expiration date stated in the existing license (or, for those licenses subject to subsection (2)(a) of this rule, before the deemed expiration date in that section), the existing license expires at the end of the day on which the Authority makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.¶
(b) Each specific license that has an expiration date after July 1, 1995, and is not one of the licenses described in subsection (1)(c) of this rule, shall be deemed to have an expiration date that is five years after the expiration date stated in the current license.¶
(c) The following specific licenses are not subject to, or otherwise affected by, the provisions of subsection (1)(b) of this rule:¶
(A) Specific licenses for which, on February 15, 1996, an evaluation or an emergency plan is required in accordance with OAR 333-102-0190(10);¶
(B) Specific licenses whose holders are subject to the financial assurance requirements specified in OAR 333-102-0200(6), and on February 15, 1996, the holders either:¶
(i) Have not submitted a decommissioning funding plan or certification of financial assurance for decommissioning; or¶
(ii) Have not received written notice that the decommissioning funding plan or certification of financial assurance for decommissioning is acceptable;¶
(C) Specific licenses who need an environmental assessment or environmental impact statement pursuant to OAR 333-102-0200(5);¶
(D) Specific licenses whose holders have not had at least one Authority inspection of licensed activities before February 15, 1996;¶
(E) Specific licenses whose holders, as the result of the most recent Authority inspection of licensed activities conducted before February 15, 1996, have been:¶
(i) Cited for a serious health and safety noncompliance;¶
(ii) Subject to an Order issued by the Authority; or¶
(iii) Subject to a Confirmatory Action Letter issued by the Authority.¶
(F) Specific licenses with expiration dates before July 1, 1995, for which the holders have submitted applications for renewal under OAR 333-102-0315.¶
(2) Each specific license revoked by the Authority expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise

provided by Authority Order.¶
(3) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material or source material until the Authority notifies the licensee in writing that the license is terminated. During this time, the licensee must:¶
(a) Limit actions involving material to those related to decommissioning; and¶
(b) Continue to control entry to restricted areas until they are suitable for release in accordance with Authority requirements.¶
(4) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in OAR 333-100-0045, each licensee must provide notification to the Authority in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Authority requirements, or submit within 12 months of notification a decommissioning plan, if required by subsection (7)(a) of this rule, and begin decommissioning upon approval of that plan if:¶
(a) The license has expired pursuant to sections (1) or (2) of this rule; or¶
(b) The licensee has decided to permanently cease principal activities, as defined in OAR 333-102-0203, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements; or¶
(c) No principal activities under the license have been conducted for a period of 24 months; or¶
(d) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Authority requirements.¶
(5) Coincident with the notification required by section (4) of this rule, the licensee must maintain in effect all decommissioning financial assurances established by the licensee pursuant to OAR 333-102-0200(6) in conjunction with a license issuance or renewal or as required by this rule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (7)(d)(E) of this rule.¶
(a) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan must do so when this rule becomes effective November 24, 1995.¶
(b) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Authority.¶
(6) The Authority may grant a request to extend the time periods established in section (4) of this rule if the Authority determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to section (4) of this rule. The schedule for decommissioning set forth in section (4) of this rule may not commence until the Authority has made a determination on the request.¶
(7)(a) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Authority and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:¶
(A) Procedures may involve techniques not applied routinely during cleanup or maintenance operations;¶
(B) Workers that may be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;¶
(C) Procedures could result in significantly greater airborne concentrations of radioactive material or source material than are present during operation; or¶
(D) Procedures could result in significantly greater releases of radioactive material or source material to the environment than those associated with operation.¶
(b) The Authority may approve an alternate schedule for submittal of a decommissioning plan required pursuant to section (4) of this rule if the Authority determines that the alternative schedule is necessary to the effective

conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.¶
(c) Procedures such as those listed in subsection (7)(a) of this rule with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.¶
(d) The proposed decommissioning plan for the site or separate building or outdoor area must include:¶
(A) A description to the extent practical, how operations will be conducted to minimize the introduction of residual radioactivity into the site including the subsurface; ¶
(B) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;¶
(~~B~~C) A description of planned decommissioning activities;¶
(~~C~~D) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;¶
(~~D~~E) A description of the planned final radiation survey; and¶
(~~E~~F) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.¶
(~~F~~G) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan must include a justification for the delay based on the criteria in section (9) of this rule.¶
(e) The proposed decommissioning plan will be approved by the Authority if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.¶
(8)(a) Except as provided in section (9) of this rule, licensees must complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.¶
(b) Except as provided in section (9) of this rule, when decommissioning involves the entire site, the licensee must request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.¶
(9) The Authority may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Authority determines that the alternative is warranted by consideration of the following:¶
(a) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;¶
(b) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;¶
(c) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;¶
(d) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and¶
(e) Other site-specific factors which the Authority may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.¶
(10) As the final step in decommissioning, the licensee must:¶
(a) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and¶
(b) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E. The licensee must, as appropriate:¶
(A) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces,

and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and¶
(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.¶
(11) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Authority determines that:¶
(a) Radioactive material or source material has been properly disposed;¶
(b) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and¶
(c)(A) A radiation survey has been performed that demonstrates that the premises are suitable for release or establishes the level of residual activity in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E; or¶
(B) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:¶
(i) Funds placed into an account separate from the licensee's assets and outside of the licensee's control before the start of decommissioning operations; or¶
(ii) A statement of intent containing a cost estimate for decommissioning or an amount based on the table in paragraph (d) of 10 CFR section 30.35(d), and indicating that funds for decommissioning will be obtained when necessary; or¶
(iii) An arrangement deemed acceptable by the governmental entity that is assuming custody and ownership of a site.¶
(~~C~~12) Alternate criteria for license termination. The Authority will terminate a license using alternate criteria greater than the dose criterion of OAR 333-102-0310, if the licensee:¶
(~~i~~a) Provides assurance that public health and safety shall continue to be protected and that it is unlikely that the total effective dose equivalent from all combined man-made sources other than medical sources shall be more than 100 millirem per year (1 millisievert per year) by submitting an analysis of possible sources of exposure;¶
(~~ii~~b) Has employed restrictions on site use in minimizing exposures at the site;¶
(~~iii~~c) Reduces doses to ALARA levels considering any detriments such as traffic accidents potentially expected to result from decontamination and waste disposal; and¶
(~~D~~d) Has submitted a decommissioning or license termination plan to the Authority indicating the licensee's intent to decommission as specified in OAR 333-102-0310, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the license termination or decommissioning plan how the advice of individuals and institutions in the community who could be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice in:¶
(~~i~~A) Participation by representatives of a broad cross section of community interests who could be affected by the decommissioning;¶
(~~ii~~B) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and¶
(~~iii~~C) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement on the issues.¶
(~~E~~e) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. ¶
(f) The use of alternate criteria to terminate a license requires the approval of the Authority after consideration of any comments provided by the U. S. Environmental Protection Agency and any public comments submitted.¶
(~~F~~g) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR Part 20, Subpart E.¶
(~~d~~h) The licensee has kept records of receipt, transfer, and disposal of radioactive material or source material, pursuant to OAR 333-100-0055 that meet the following criteria:¶
(A) The licensee must retain each record of receipt of radioactive material or source material as long as the

material is possessed and for three years following transfer or disposal of the material.¶
(B) The licensee who transferred the material must retain each record of transfer for three years after each transfer unless a specific requirement in another part of the rules in this chapter dictates otherwise.¶
(C) The licensee who disposed of the material must retain each record of disposal of byproduct material until the Authority terminates each license that authorizes disposal of the material.
Statutory/Other Authority: ORS 453.635, 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-0880

RULE SUMMARY: OAR 333-116-0880, Training and Experience for PET, PET/CT and SPECT/CT Personnel. Authorized Users who have a board specialty certificate will not be required 40 additional hours of training PET operations.

CHANGES TO RULE:

333-116-0880
~~Specific Requirements for Positron Emission Tomography (PET) Facilities:~~ Training and Experience for PET, PET/CT and SPECT/CT Personnel ¶

(1) Pharmacy or chemistry personnel must have 40 extra hours above Nuclear Pharmacy requirements and 40 hours specific to PET. The 40 hours can be divided equally between didactic and practical applications.¶
(2) ~~Authorized users who meet training requirements for human use in OAR 333-116-0670 must complete an additional 40 hours at an accepted PET training center.¶~~
~~(3)~~ Technical personnel working under an authorized user must have basic radiation safety training, plus 40 additional hours specific to PET.¶
(4~~3~~) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems must be operated by technologists licensed by the Oregon Board of Medical Imaging who are:¶
(a) Any registered radiographer with the credential R.T. (R);¶
(b) Registered radiation therapist with the credential R.T. (T);¶
(c) Registered certified nuclear medicine technologist with the credentials R.T. (N); or¶
(d) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).¶
(~~5~~4) The individuals mentioned in section (4~~3~~) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.¶
(~~6~~5)(a) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Authority; and¶
(b) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or¶
(c) Individuals meeting the requirements of section (4~~3~~) of this rule and who have successfully completed training that the Authority has evaluated and judged to be substantially equivalent to that specified in subsection (6)(a) of this rule.¶
(~~7~~6) An R.T. (N) or CNMT certified in Computed Tomography through the American Registry of Radiologic Technologists is considered to have met the training requirements in section (4~~3~~) of this rule.¶
(~~8~~7) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-118-0020

RULE SUMMARY: OAR 333-118-0020, Definitions. To be compatible with 10 CFR Part 71.4; insert the term “excluding any shielding does not exceed 2 x 10-3 A2 per gram”.

CHANGES TO RULE:

333-118-0020
Definitions ¶

As used in this division, the following definitions apply: ¶
(1) "A1" means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in Appendix A to10 CFR Part 71, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71. ¶
(2) "A2" means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in Appendix A to10 CFR Part 71, Table A-1, or may be derived in accordance with the procedures prescribed in Appendix A to10 CFR Part 71. ¶
(3) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft. ¶
(4) "Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type. ¶
(5) "Consignment" means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport. ¶
(6) "Contamination" means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm2 (1 □ 10-5 □Ci/cm2) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm2 (1 □ 10-6 □Ci/cm2) for all other alpha emitters.¶
(a) Fixed contamination means contamination that cannot be removed from a surface during normal conditions of transport.¶
(b) Non-fixed contamination means contamination that can be removed from a surface during normal conditions of transport.¶
(7) "Conveyance" means for transport by public highway or rail any transport vehicle or large freight container; or for transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; or for transport by aircraft. ¶
(8) "Criticality Safety Index (CSI)" means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of criticality safety index is described in 10 CFR 71.22, 71.23, and 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.¶
(9) "Deuterium" means for the purposes of 10 CFR Parts 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000. ¶
(10) "Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor. ¶
NOTE: The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other

regulations, such as Title 49 of the Code of Federal Regulations. ¶
(11) "Fissile material" means the radionuclides plutonium-239, plutonium-241, uranium-233, and uranium-235, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in 10 CFR 71.15.¶
NOTE: Authority jurisdiction is limited to special nuclear material in quantities not sufficient to form a critical mass as defined in division 100 of this chapter. ¶
(12) "Fissile material package" means a fissile material packaging together with its fissile material contents. ¶
(13) "Graphite" means for the purposes of OAR 333-118-0053 and OAR 333-118-0110, graphite with a boron equivalent content less than five parts per million and density greater than 1.5 grams per cubic centimeter. ¶
(14) "Indian ŧTribe" means an Indian or Alaska Native ŧTribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian ŧTribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a. ¶
(15) "Licensed material" means radioactive or special nuclear material received, possessed, used, or transferred under a general or specific license issued by the Authority. ¶
NOTE: The definition of licensed material in this division is used in the same way as in 49 CFR 173.403. ¶
(16) "Low specific activity (LSA) material" means radioactive material with limited specific activity that is nonfissile or is excepted under OAR 333-118-0053, and that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups: ¶
(a) LSA-I: ¶
(A) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides; ¶
(B) Natural uranium, depleted uranium, natural thorium, or their compounds or mixtures; provided they are unirradiated and in solid or liquid form;¶
(C) Radioactive material, other than fissile material, for which the A2 value is unlimited; or ¶
(D) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 10 CFR 71, Appendix A. ¶
(b) LSA-II: ¶
(A) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or ¶
(B) Other radioactive material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10-4 A2/g for solids and gases, and 10-5 A2/g for liquids. ¶
(c) LSA-III. Solids (consolidated wastes, activated materials) excluding powders that satisfy the requirements of 10 CFR Part 71.77 in which: ¶
(A) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, and ceramic); ¶
(B) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, shall not exceed 0.1 A2; and ¶
(C) The estimated average specific activity of the solid, excluding any shielding, does not exceed 2 x 10-3 A2 per gram. ¶
(17) "Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than 10 days. ¶
(18) "Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232). ¶
(19) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as

"special form radioactive material." ¶
(20) "Package" means the packaging together with its radioactive contents as presented for transport. ¶
(a) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents. ¶
(b) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR part 173. ¶
(c) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs/in2) gauge or a pressure relief device that may allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it shall receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19. ¶
(21) "Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of 10 CFR Part 71.4. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging. ¶
(22) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397. ¶
(23) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71. ¶
(24) "Special form radioactive material" means radioactive material that satisfies the following conditions: ¶
(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule; ¶
(b) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch.); and ¶
(c) It satisfies the requirements of 10 CFR Part 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR Part 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of 10 CFR Part 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form materials that were successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR Part 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition. ¶
(25) "Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material. ¶
(26) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. ¶
(27) "Surface contaminated object (SCO)" means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits: ¶
(a) SCO-I: a solid object on which: ¶
(A) The non-fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4 Bq/cm2 (10-4 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 0.4 Bq/cm2 (10-5 microcurie/cm2) for all other alpha emitters; ¶
(B) The fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 4x104 Bq/cm2 (1.0 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 4x103 Bq/cm2 (0.1 microcurie/cm2) for all other alpha emitters; and ¶
(C) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2

(or the area of the surface if less than 300 cm2) does not exceed 4x104 Bq/cm2 (1 microcurie/cm2) for beta, gamma and low toxicity alpha emitters, or 4x103 Bq/cm2 (0.1 microcurie/cm2) for all other alpha emitters. ¶
(b) SCO-II: a solid object on which the limits for SCO-I are exceeded and on which: ¶
(A) The nonfixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 400 Bq/cm2 (10-2 microcurie/cm2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm2 (10-3 microcurie/cm2) for all other alpha emitters; ¶
(B) The fixed contamination on the accessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 microcuries/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 microcuries/cm2) for all other alpha emitters; and ¶
(C) The nonfixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm2 (or the area of the surface if less than 300 cm2) does not exceed 8 x 105 Bq/cm2 (20 microcuries/cm2) for beta and gamma and low toxicity alpha emitters, or 8 x 104 Bq/cm2 (2 microcuries/cm2) for all other alpha emitters. ¶
(28) "Transport index (TI)" means the dimensionless number, (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)). ¶
(29) "Tribal official" means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership. ¶
(30) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material or A2 for normal form radioactive material, where A1 and A2 are given in 10 CFR Part 71 Appendix A or may be determined by procedures described in 10 CFR Part 71 Appendix A. ¶
(31) "Type A package" means a packaging that, together with its radioactive contents limited to A1 or A2 as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding under normal conditions of transport as demonstrated by the tests set forth in 173.465 or 173.466, as appropriate. ¶
(32) "Type B package" means a Type B packaging together with its radioactive contents. ¶
NOTE: A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in OAR 333-118-0035. ¶
(33) "Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71. ¶
(34) "Type B quantity" means a quantity of radioactive material greater than Type A quantity. ¶
NOTE: 10 CFR Part 71 Appendix A referred to or incorporated by reference in this rule is attached to this division or available from the Authority. ¶
(35) "Unirradiated uranium" means uranium containing not more than 2E+3 Bq of plutonium per gram of uranium-235, not more than 9E+6 Bq of fission products per gram of uranium-235, and not more than 5E-3 g of uranium-236 per gram of uranium-235. ¶
(36) "Uranium - natural, depleted, enriched": ¶
(a) "Natural uranium" means uranium (which may be chemically separated) with the naturally occurring distribution of uranium, isotopes (which is approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238). ¶
(b) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes. ¶
(c) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of

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

AMEND: 333-118-0070

RULE SUMMARY: OAR 333-118-0070, General License: Nuclear Regulatory Commission-Approved Packages. To be compatible with 10 CFR Part 71.17; insert the term “Regulatory” within the rule and provide Radiation Protection Services contact information.

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: Radiation Protection Services, 800 NE Oregon St. Suite 640, Portland Oregon 97232, 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: 333-120-0200

RULE SUMMARY: OAR 333-120-0200, Surveys and Monitoring: General. To be compatible with 10 CFR Part 20.1501; insert to 10 CFR, "Parts 50.75(g), 70.25(g) or 72.30(d) as applicable".

CHANGES TO RULE:

333-120-0200
Surveys and Monitoring: General ¶

(1) Each licensee or registrant must make or cause to be made, surveys that: ¶
(a) Are necessary for the licensee or registrant to comply with the rules in this division; and ¶
(b) Are reasonable under the circumstances to evaluate: ¶
(A) The magnitude and extent of radiation levels; and ¶
(B) The concentrations or quantities of radioactive material; and ¶
(C) The potential radiological hazards that could be present. ¶
(2) Notwithstanding OAR 333-120-0620, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning. Records must be retained in accordance with 10 CFR parts 30.35(g), 40.36(f), ~~and 70.25(g)~~50.75(g), 70.25(g) or 72.30(d) as applicable. ¶
(3) The licensee or registrant must ensure that instruments and equipment used for quantitative radiation measurements (such as dose rate and effluent monitoring) are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable division or a license condition. ¶
(4) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with OAR 333-120-0100, with other applicable provisions of this division or with conditions specified in a license must be processed and evaluated by a dosimetry processor: ¶
(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and ¶
(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored. ¶
(5) The licensee or registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0210

RULE SUMMARY: OAR 333-120-0210, Surveys and Monitoring: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose. Remove the requirement of "Individuals working with medical fluoroscopic equipment", and remove the redundant term within the rule of "The second individual monitoring device is required for a declared pregnant woman". Registrants will need to demonstrate that occupational dose remains below 10% of the total allowable dose in one year to discontinue the use of monitoring during fluoroscopic operations.

CHANGES TO RULE:

333-120-0210
Surveys and Monitoring: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose ¶

Each licensee or registrant must monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this division. As a minimum: ¶
(1) Each licensee or registrant must monitor occupational exposure to radiation and must supply and require the use of individual monitoring devices by: ¶
(a) Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in OAR 333-120-0100(1); ¶
(b) Minors likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in OAR 333-120-0160 or 333-120-0170; ¶
(c) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem)~~;~~¶
~~(d) Individuals entering a high or very high radiation area; and~~¶
~~(e) Individuals working with medical fluoroscopic equipment.~~¶
~~(A).~~ An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to OAR 333-120-0170(1), must be located under the protective apron at the waist~~.~~; and ¶
(d) Individuals entering a high or very high radiation area. ¶
(~~B~~2) An individual monitoring device used for lens dose equivalent must be located at the neck, or an unshielded location closer to the lens, outside the protective apron. ¶
(~~C~~3) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to OAR 333-120-0100(3)(b) it must be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it must be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman. ¶
(~~2~~4) Each licensee or registrant must monitor (OAR 333-120-0130) the occupational intake of radioactive material by and assess the committed effective dose equivalent to: ¶
(a) Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI(s) in 10 CFR Part 20 Table 1, Columns 1 and 2, of Appendix B to 20.1001 to 20.2401; and ¶
(b) Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of one mSv (0.1 rem), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv). ¶
(c) Declared pregnant women likely to receive, during the entire pregnancy, from radiation sources external to the body, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).¶
~~[ED. NOTE: Appendices referenced are available from the agency.]~~
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-120-0320

RULE SUMMARY: OAR 333-120-0320, Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas: Use of Individual Respiratory Protection Equipment, federal requirement. To be compatible with 10 CFR 20.1703; remove the term “exposure” and insert the term “doses”. Insert the term “greater than or equal to 10 times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure”, and insert the term “or at a frequency determined by a physician”.

CHANGES TO RULE:

333-120-0320
Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas: Use of Individual Respiratory Protection Equipment ¶

(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to OAR 333-120-0310: ¶
(a) The licensee must use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA). ¶
(b) The licensee may use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee must submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. ¶
(c) The licensee must implement and maintain a respiratory protection program that includes: ¶
(A) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate ~~exposur~~doses; and ¶
(B) Surveys and bioassays, as appropriate, to evaluate actual intakes; and ¶
(C) Testing of respirators for operability immediately prior to each use; and ¶
(D) Written procedures regarding: ¶
(i) Monitoring, including air sampling and bioassays; ¶
(ii) Supervision and training of respirator users; ¶
(iii) Fit testing; ¶
(iv) Respirator selection; ¶
(v) Breathing air quality; ¶
(vi) Inventory and control; ¶
(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment; ¶
(viii) Recordkeeping; and ¶
(ix) Limitations on periods of respirator use and relief from respirator use; and ¶
(E) Determination by a physician prior to initial fitting and use of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment. ¶
(F) Fit testing, with fit factor ~~>~~greater than or equal to 10 times the APF for negative pressure devices, and a fit factor ~~>~~greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one year, or at a frequency determined by a physician. Fit testing must be performed with the facepiece operating in the negative pressure mode. ¶
(d) The licensee must issue a written policy statement on respirator usage covering: ¶
(A) The use of process or other engineering controls, instead of respirators; and ¶
(B) The routine, nonroutine, and emergency use of respirators; and ¶
(C) The periods of respirator use and relief from respirator use. ¶
(e) The licensee must advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or

communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief. ¶
(f) The licensee must use equipment within limitations for type and mode of use and must provide proper visual, communication, low temperature work environments, the concurrent use of safety or radiological protection equipment and other special capabilities (such as adequate skin protection) when needed. The licensee must ensure equipment is used in such a way as not to interfere with the proper operation of the respirator. ¶
(2) In estimating exposure of individuals to airborne radioactive materials, the licensee or registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to OAR 333-120-0310, provided that the following conditions, in addition to those in section (1) of this rule, are satisfied: ¶
(a) The licensee selects respiratory protection equipment that provides a protection factor (10 CFR Part 20 Appendix A to 20.1001 to 20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in 10 CFR Part 20 Table 1, Column 3 of Appendix B to 20.1001 to 20.2401. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in OAR 333-120-0310 of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used; and ¶
(b) The licensee must obtain authorization from the Authority before assigning respiratory protection factors in excess of those specified in 10 CFR Part 20 Appendix A to 20.1001 to 20.2401. The Authority may authorize a licensee to use higher protection factors on receipt of an application that: ¶
(A) Describes the situation for which a need exists for higher protection factors; and ¶
(B) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use. ¶
(3) The licensee must use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA. ¶
(4) The licensee must notify the Authority, in writing, at least 30 days before the date that respiratory protection equipment is first used under the provisions of either sections (1) or (2) of this rule. ¶
(5) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons must observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed. ¶
(6) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997. Grade D quality air criteria include: ¶
(a) Oxygen content (v/v) of 19.5-23.5%; ¶
(b) Hydrocarbon (condensed) content of five milligrams per cubic meter of air or less; ¶
(c) Carbon monoxide (CO) content of 10 ppm or less; ¶
(d) Carbon dioxide content of 1,000 ppm or less; and ¶
(e) Lack of noticeable odor. ¶
(7) The licensee must ensure that no objects, materials or substances, such as facial hair, or any conditions that

interfere with the facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.¶
(8) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-124-0010

RULE SUMMARY: OAR 333-124-0010, Civil Penalties. Rule requested by the Attorney General's Office; insert section within the rule to read "Persons may be subject to a civil penalty without being issued a Notice of Violation for violations of OAR 333-101-0005, OAR 333-101-0020, OAR 333-101-0023 OAR 333-101-0045, OAR 333-102-0001, OAR 333-119-0020, or any violation within OAR chapter 333, division 103".

CHANGES TO RULE:

333-124-0010
Civil Penalties ¶

(1) The Authority may impose a civil penalty on: ¶
(a) A tanning facility for violations of ORS 431.925 through 431.955 or any rules in divisions 100, 103, 111, 119 and this chapter. ¶
(b) An X-ray machine registrant for a violation of ORS 453.605 through 453.807 or any rules in division 100, 101, 103, 106, 108, 111, 112, 115, 120, 122, 123 of this chapter, and this division. ¶
(c) A radioactive materials licensee for a violation of ORS 453.605 through 453.807 or any rules in divisions 100, 102, 103, 105, 109, 111, 113, 116, 117, 118, 120, 121 of this chapter, and this division. ¶
(2) For a first violation, unless the violation poses a serious public health threat, the Authority shall provide a tanning facility, X-ray machine registrant or radioactive materials licensee with a Notice of Violation that explains the violation and informs the facility, registrant or licensee of the violation and that it must be corrected within a time frame specified in the Notice, or the facility, registrant or licensee may be subject to a civil penalty. ¶
(3) Persons may be subject to a civil penalty without being issued a Notice of Violation for violations of OAR 333-101-0005, OAR 333-101-0020, OAR 333-101-0023 OAR 333-101-0045, OAR 333-102-0001, OAR 333-119-0020, or any violation within OAR chapter 333, division 103. ¶
(4) For violations that pose a significant public health threat, or for second or subsequent violations of any level of severity, the Authority may, but is not required to, issue a Notice of Violation as described in section (2) of this rule prior to issuing a Notice of Imposition of Civil Penalty. ¶
(45) Each day that a facility, registrant or licensee is in violation is considered a new violation until the facility, registrant or licensee is in compliance. ¶
(~~5~~6) Each device that is out of compliance with applicable statutes or rules is a separate violation. ¶
(~~6~~7) A civil penalty will be imposed based on the severity of the violation and whether it is a first or repeat offense. ¶
(a) Level 1 violation: A violation that has the potential to cause a significant health and safety problem or has caused a significant health and safety problem. ¶
(b) Level 2 violation: A violation that has the potential to cause a moderate health and safety problem or has caused a moderate health and safety problem. ¶
(c) Level 3 violation: A violation that has the potential to cause a minor health and safety problem or has caused a minor health and safety problem. ¶
(d) Level 4 violation: A violation that, if it continues, could result in a condition that may cause a health and safety problem. ¶
(e) Level 5 violation: An action that violates a statute or rule but will not result in a direct health and safety problem. (Minor statutory or administrative rule infraction) ¶
(~~7~~8) Civil penalty amounts are as follows, except as provided in section (8) of this rule: ¶
(a) Level 1 violation, first offense: $200.~~00.~~ ¶
(b) Level 1 violation, second offense: $350.~~00.~~ ¶
(c) Level 1 violation, third and subsequent offenses: $500.~~00.~~ ¶
(d) Level 2 violation, first offense: $150.~~00.~~ ¶
(e) Level 2 violation, second offense: $200.~~00.~~ ¶
(f) Level 2 violation, third and subsequent offenses: $250.~~00.~~ ¶

(g) Level 3 violation: $100.~~00.~~ ¶
(h) Level 3 violation, second offense: $150.~~00.~~ ¶
(i) Level 3 violation, third and subsequent offenses: $200.~~00.~~ ¶
(j) Level 4 violation, first offense: $75.~~00.~~ ¶
(k) Level 4 violation, second offense: $100.~~00.~~ ¶
(l) Level 4 violation, third and subsequent offenses: $125.~~00.~~ ¶
(m) Level 5 violation, first offense: $50.~~00.~~ ¶
(n) Level 5 violation, second offense: $75.~~00.~~ ¶
(o) Level 5 violation, third and subsequent offenses: $100.~~00.~~ ¶
(~~8~~9) For failure to properly pay registration or licensing fee in whole within 30 days of the due date, the registrant or licensee will be subject to a civil penalty of: ¶
(a) Three percent of the applicable fee outlined in division 103 of these rules per day per device for the first 30 days, followed by; ¶
(b) Five percent of the applicable fee outlined in division 103 of these rules per day per device for the next 30 days, followed by; ¶
(c) Ten percent of the applicable fee outlined in division 103 of these rules per day per device for the next 30 days or subsequent periods and calculated from the due date until the registration or licensing fee is paid in full. ¶
(~~9~~10) The Authority will issue a Notice of Intent to Assess Civil Penalties and the Notice will explain the right of the facility to request a hearing, in accordance with ORS 183.745.
Statutory/Other Authority: ORS 431.262, 431.950, 453.771
Statutes/Other Implemented: ORS 431.262, 431.950, 453.771

AMEND: 333-125-0080

RULE SUMMARY: OAR 333-125-0080, Background Investigations and Access Control Program: Procedures for Processing of Fingerprint Checks. Change the Nuclear Regulatory Commission's address to submit fingerprint cards.

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~~Criminal History Program, Division of Facilities and Security, 11545 Rockville Pike, ~~ATTN: Criminal History Program/~~Mail Stop T-~~03B467~~D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by electronic mail to FORMS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at http://www.nrc.gov/site-help/e-submittals.html.¶
(2) Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at 301-415-7513. Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Electronic Submittals page at http://www.nrc.gov/site-help/e-submittals.html and see the link for the Criminal History Program under Electronic Submission Systems.)¶
(3) The Commission shall forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.635

AMEND: 333-125-0180

RULE SUMMARY: OAR 333-125-0180, Physical Protection in Transit: Advance Notification of Shipment of Category 1 Quantities of Radioactive Material. To be compatible with 10 CFR Part 37.77; rule refers to OAR 333-125-0120(1), remove section (1) from the rule number.

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. ¶
(a) Procedures for submitting advance notification. The notification must be made to the Authority and to the office of each appropriate Governor or Governor's designee. The contact information, including telephone and mailing addresses, of Governors and Governors' designees, is available on the NRC's website at https://scp.nrc.gov/special/designee.pdf.~~.~~ A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.¶
(b) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility. ¶
(c) A notification delivered by any means other than mail must reach NRC at least four days before the transport of the shipment commences and must reach the office of the Governor or the Governor's designee at least four days before transport of a shipment within or through the state. ¶
(2) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification: ¶
(a) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material; ¶
(b) The license numbers of the shipper and receiver; ¶
(c) A description of the radioactive material contained in the shipment, including the radionuclides and quantity; ¶
(d) The point of origin of the shipment and the estimated time and date that shipment will commence; ¶
(e) The estimated time and date that the shipment is expected to enter each state along the route; ¶
(f) The estimated time and date of arrival of the shipment at the destination; and ¶
(g) A point of contact, with a telephone number, for current shipment information. ¶
(3)(a) Revision notice. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Governor of the state or the Governor's designee and to the Authority. ¶
(b) A licensee shall promptly notify the Governor of the state or the Governor's designee of any changes to the information provided in accordance with sections (2) and (3) of this rule. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes. ¶
(4) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the Governor of each state or to the Governor's designee previously notified and to the Authority. The licensee shall send the cancellation notice before the shipment has commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled. ¶
(5) Records. The licensee shall retain a copy of the advance notification, any revision and cancellation notices as a

record for three years after the notification has been made. ¶
(6) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the U.S. Nuclear Regulatory Commission or an Agreement State, who receive schedule information of the kind specified in section (2) of this rule shall protect that information against unauthorized disclosure as specified in OAR 333-125-0120~~(1)~~.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.635