Attachment 1

Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Public Health Division — 333

Agency and Division — Administrative Rules Chapter Number

Rule Caption
Update Radiation Protection Services' X-ray and radioactive materials program rules

In the Matter of: Amending, repealing and adopting rules in Oregon Administrative Rules chapter 333, divisions 100, 101, 102, 103, 106, 116, 118 and 120 pertaining to Radiation Protection Services (RPS).

Statutory Authority: ORS 453.605 – 453.807
Other Authority: Nuclear Regulatory Commission's 10 CFR Parts 35 and 71.
Stats. Implemented: ORS 453.605 – 453.807

Need for the Rule(s):
The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to amend, adopt and repeal Oregon Administrative Rules relating to the X-ray and radioactive materials programs within the RPS section.

The Radiation Materials Licensing (RML) program is proposing to amend rules to comply with the Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 and 71, within divisions 116 and 118. The amendments are in reference to providing advanced notification to Native American Tribes of the transportation of certain types of nuclear material. These amendments will also correct rule references relating to 10 CFR Part 35, in regards to Authorized User training requirements to administer byproduct materials to patients for medical diagnosis and treatment.

Chapter 333, division 103 is being amended to increase annual radioactive materials licensing fees by 25 percent. During the 2011-2013 fiscal biennium, furloughs and cost adjustment freezes were implemented. RPS's RML program ended the 2011-2013 biennium with an ending balance of $165,357 which carried over into the 2013-2015 biennium. This resulted in a 56 percent decrease compared to the 2009-2011 carryover balance.

The projected 2013-2015 biennium expenditure budget has a projected 13.5 percent increase for personal services. The projected 2013-2015 ending balance will be a negative $3,841. It is estimated that the RML program will need to generate an additional $322,541 in addition to the previous biennium revenue of $1,635,549 to meet future expenditures.

The RML program revenue is 100 percent dependent on user fees collected annually from radioactive material licensees. There are no general or federal funds provided to support operations. The fees are in direct relation with services involved in regulating the radioactive material industry. License fees are assessed to recover the cost of operations and administrative functions relating to the regulation of the medical, academia, industrial, and research industries that use radioactive materials as part of their operations.

The X-ray program is adopting, repealing and amending rules in division 106 to align current computed tomography (CT) rules with emerging technology and address the use of the veterinary X-ray technique chart.

Documents Relied Upon, and where they are available:
* Nuclear Regulatory Commission's Regulation Amendments (RATS) 2009-1 and 2012-2:
http://nrc-stp.ornl.gov/rss_regamendments.html
* 10 CFR Parts 1-50:

Conference of Radiation Control Program Directors, Inc., State Suggested Regulations:
http://www.crcpd.org/SSRCRs/F-Part%202009.pdf

H-32 Task Force for Computed Tomography, Conference of Radiation Control Program Directors Inc.:
www.crcpd.org

Fiscal and Economic Impact:

RPS does not anticipate any impacts to radioactive material licensees by clarifying OARs relating to the NRC's 10 CFR Parts 35 and 71 by correcting rule cross referencing pertaining to the training requirements to providers who administer byproduct materials for medical use. RPS must have compatible rules with NRC's regulations.

Division 103 will direct radioactive materials licensing fees to be increased by 25 percent to cover current expenditures. No single fee will exceed $3,000 without future legislative approval.

Division 106 will have no economic impact relating to the revision of rules addressing computed tomography and veterinary technique charts since these systems are currently in place.

RPS currently has the ability to absorb these additional requirements within the licensing, registration and enforcement programs, and does not anticipate any adverse impacts affecting the Oregon Health Authority.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2) (b) (E)):
There is no anticipated cost of compliance on state agencies or units of local government. Radioactive material licensees will be affected by the 25 percent increase in fees relating to facilities using and storing radioactive materials. .

2. Cost of compliance effect on small business (ORS 183.336):
a. Estimate the number of small businesses and types of businesses and industries with small businesses subject to the rule:

The radioactive materials industry is a mixture of small and large businesses using radioactive materials for the purposes of medical research, soil studies, medical diagnostics and medical care and industries providing non-destructive testing services. RPS does not track data in relation to small or large businesses using radioactive materials. It is estimated that 351 radioactive material licensees will be impacted by the licensing fee increase.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

There are no additional administrative requirements with the proposed amended rules relating to radioactive material licensees and X-ray device registrants.

c. Equipment, supplies, labor and increased administration required for compliance:
There is no need for an increase in administrative services nor any additional equipment, supplies or labor needed for compliance. Current regulatory practices will be unaffected with the adoption and amendment of the administrative rules.

How were small businesses involved in the development of this rule?
The State of Oregon Radiation Advisory Committee which has members representing various radioactive material industries and stakeholders met in June 2013 to review the proposed fee schedule changes. Members supported the need for increasing RML fees to maintain current operations. The last fee increase of 17 percent was adopted in rule in July 2010.

Administrative Rule Advisory Committee consulted?: Yes
The following industries and special interest groups were represented by:
Legacy Health Systems,
Oregon State University Radiation Center,
Kaiser Permanente,
Oregon Health Science University,
Oregon State University Radioactive Materials Program,
Suns Up Tanning.

Alayna Nest, Administrative Rules Coordinator

Signature | Printed name | Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2007

DRAFT

Secretary of State

NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form.

Oregon Health Authority, Public Health Division		333
Agency and Division		Administrative Rules Chapter Number
Alayna Nest	800 NE Oregon St., Suite 930, Portland, Oregon, 97232	971-673-1291
Rules Coordinator	Address	Telephone

RULE CAPTION

Update Radiation Protection Services' X-ray and radioactive materials program rules. **Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.**

July 16, 2014	9:00 AM	800 NE Oregon St., Room 221, Portland, Oregon 97232	Jana Fussell
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

ADOPT: 333-106-0345, 333-106-0361, 333-106-0362, 333-106-0363, 333-106-0364, 333-106-0366, 333-106-0367, 333-106-0368 and 333-106-0369.

AMEND: 333-100-0020, 333-101-0003, 333-101-0020, 333-102-0300, 333-103-0003, 333-103-0010, 333-103-0015, 333-103-0030, 333-103-0035, 333-106-0015, 333-106-0055, 333-106-0325, 333-106-0350, 333-106-0355, 333-106-0360, 333-116-0045, 333-116-0190, 333-116-0680, 333-116-0683 333-116-0687, 333-116-0690, 333-118-0020, 333-118-0190 and 333-120-0710.

Repeal: 333-106-0365

Stat. Auth. : ORS 431.925- 431.955 and 453.605-453.807

Other Auth.: 10 CFR Parts 1-50

Stats. Implemented: ORS 453.605- 453.807

RULE SUMMARY

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to amend and adopt Oregon Administrative Rules related to the radioactive material licensing and X-ray programs within the Radiation Protection Services.

The Radiation Materials Licensing (RML) program is proposing to amend rules to comply with the Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 and 71, within divisions 116 and 118. The amendments are in reference to providing advanced notification to Native American Tribes of the transportation of certain types of nuclear material. These amendments will also correct rule references relating to 10 CFR Part 35, in regards to Authorized User training requirements to administer byproduct materials to patients for medical diagnosis and treatment.

Chapter 333, division 103 is being amended to increase annual radioactive materials licensing fees by 25 percent. During the 2011-2013 fiscal biennium, furloughs and cost adjustment freezes were implemented. RPS's RML program ended the 2011-2013 biennium with an ending balance of $165,357 which carried over into the 2013-2015 biennium. This resulted in a 56 percent decrease compared to the 2009-2011 carryover balance.

The projected 2013-2015 biennium expenditure budget has a projected 13.5 percent increase for personal services. The projected 2013-2015 ending balance will be a negative $3,841. It is estimated that the RML

program will need to generate an additional $322,541 in addition to the previous biennium revenue of $1,635,549 to meet future expenditures.

The RML program revenue is 100 percent dependent on user fees collected annually from radioactive material licensees. There are no general or federal funds provided to support operations. The fees are in direct relation with services involved in regulating the radioactive material industry. License fees are assessed to recover the cost of operations and administrative functions relating to the regulation of the medical, academia, industrial, and research industries that use radioactive materials as part of their operations.

The X-ray program is adopting, repealing and amending rules in division 106 to align current computed tomography (CT) rules with emerging technology and address the use of the veterinary X-ray technique chart.

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

July 22, 2014 by 5:00 pm

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

Alayna Nest, Administrative Rules Coordinator

Signature | Printed name | Date

*Hearing Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. ARC 920-2005

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 100

CONTROL OF RADIATION IN OREGON

General Requirements

333-100-0020
Prohibited Uses

(1) Hand-held fluoroscopic screens shall not be used unless they have been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.
(2) Shoe-fitting fluoroscopic devices shall not be used.
(3) Sources of radiation shall not be used to expose any individual solely for training or demonstration purposes.
(4) Sources of radiation shall not be used for the purpose of screening or inspecting individuals for concealed weapons, hazardous materials, stolen property, illegal goods or contraband.
(5) No person shall intentionally apply or allow to be applied, either directly or indirectly, ionizing radiation to human beings except by, or under the supervision of, persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation on humans. Notwithstanding this restriction, the Authority recognizes practitioners of the healing arts to be as outlined in ORS 676.110, that is:
(a) Podiatrists, Chiropractors, Dentists, Naturopath, Osteopaths, Medical Doctors, and Veterinarians;
(b) Nurse Practitioners and Physician Assistants may prescribe X-ray when doing so within the bounds of their independent rules;
(c) Dental Professionals are permitted to prescribe and review intraoral radiographs, in accordance with the Oregon Board of Dentistry administrative rules, chapter 818.
(d) No person shall ~~will~~ be allowed to use X-ray producing equipment without first meeting the requirements of OAR 333-106-0045(165) or 333-106-0055.
(6) No person shall intentionally or unintentionally expose another individual to radiation other than ionizing radiation in such a way as to adversely affect the health or safety of that individual. Notwithstanding this restriction, the use of radiation other than ionizing radiation by persons licensed by the State of Oregon to practice the healing arts and who are authorized to use radiation may~~will~~ be allowed.
(7) Dental units with a Kilovolt peak (kVp) of 50 and below are prohibited from being sold, leased, transferred or lent.
(a) Existing diagnostic dental X-ray systems less than 55 kVp shall not be used on minors.
(b) After October 1, 2011, registrants may not use diagnostic dental X-ray systems with a fixed, nominal kVp of less than 55.

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Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 101

REGISTRATION OF RADIATION MACHINES, GENERAL LICENSE RADIOACTIVE MATERIALS, LICENSING OF RADIATION SERVICES, AND ACCREDITATION OF HOSPITAL RADIOLOGY INSPECTORS

333-101-0003
Definitions

(1) "Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more devices or sources of radiation (X-ray, radioactive materials, or non-ionizing radiation) are installed.
(2) "Health Physics Consultant" means a person, business, facility, or institution providing health physics knowledge and skills for a fee. A health physics consultant may not use or possess radioactive material without specific license authorization pursuant to OAR 333-102-0200.
(3) "Inoperable" means disabling equipment such that ionizing radiation cannot be produced. This is accomplished by removing the X-ray tube, removal of the control unit, removal of the power supply or physical removal of the power cord on a free standing unit.
(4) "Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.
(5) "Vendor" means a person, business, facility, or institution providing a product or service for a fee. Radiation vendors include, but are not limited to, ~~-~~machine salespersons, repair and technical personnel, training providers or marketing representatives who sell, demonstrate, or market Xx-ray machines or tanning beds and provide advice, consultation, service, or technical information to registrants.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.685 & 453.761

333-101-0020
Application for License of Sales, Services, Consultation, and Servicing For Radiation Machines

(1) Each person who is engaged in the business of training, selling, leasing, transferring, lending, installing or offering to install radiation machines or tanning beds, or is engaged in the business of furnishing or offering to furnish radiation machines, X-ray automatic film processor, X-ray processing chemicals, radioactive material (unless such activities are authorized under a specific license), or tanning servicing or services in this state, must apply for license of such services with the Authority within 30 days following the effective date of this rule or thereafter prior to furnishing or offering to furnish any such services.

(2) Application for a license must be completed on forms furnished by the Authority and must contain the following information or such other information as may be required:
(a) Name, address and telephone number of the following:
(A) The individual or the company to be licensed; and
(B) The owner(s) of the company.
(b) The services ~~that~~ to ~~shall~~ ~~will~~[on] be provided;
(c) The area of the state and other states to be covered;
(d) A list of the individuals qualified to provide these services; and
(e) The date of application and signature of the individual responsible for the company, beneath a statement of the items specified in OAR 333-101-0020(3).
(3) Each person applying for license under this division must specify:
(a) That they have read and understand the requirements of these rules;
(b) The services for which they are applying for license;
(c) The training and experience that qualify them or their technical staff to discharge the services for which they are applying for license;
(A) Training for radiation machine vendors must include, but must not be limited to, a minimum of one day of training in radiation use and safety.
(B) The training specified in OAR 333-101-0020(3)(c)(A) must be taught by an Authority approved instructor. Approval must~~will~~ be based upon the following criteria;
(i) Current Radiologic Technologist license with the Oregon Board of Radiologic Technology and a minimum of two years of work experience in Radiologic Technology; and
(ii) Experience in the use of radiation measurement instruments; or
(iii) "Qualified Expert" as defined in OAR 333-100-0005; or
(iv) "Health Physics Consultant" as defined in OAR 333-101-0003.
(C) Subjects to be covered must include but not be limited to:
(i) Nature of X~~x~~-rays;
(ii) Radiation units;
(iii) Biological effects of X~~x~~-ray radiation;
(iv) Principals of radiation protection;
(v) Radiation survey instruments;
(vi) Personnel monitoring equipment; and
(vii) Applicable federal and state radiation regulations.
(d) The type of measurement instruments to be used, frequency of calibration, source of calibration; and
(e) The type of personnel dosimeters supplied, frequency of reading and replacement or exchange schedule.
(4) All radiation machine vendors who install or repair radiation machines must have measurement instruments that ~~will~~ assure compliance with all X~~x~~-ray machine, or tanning bed installation requirements according to all applicable federal standards, as well as instruments to properly check items such as collimation, HVL, kVp, mA, time, and radiation output, or assure these tests are made by a qualified expert as needed, and that the information is included in the installation report.
(5) For the purpose of OAR 333-101-0020, services may include but must not be limited to:

(a) Sales or leasing of radiation machines, installation_-and/~~or~~ servicing of radiation machines and associated radiation machine components;
(b) Calibration of radiation machines;
(c) Calibration and use of radiation measurement instruments or devices;
(d) Radiation protection or health physics consultations or surveys;
(e) Personnel dosimetry services (not otherwise licensed under these rules);
(f) Installation and/~~or~~ servicing of automatic X~~x~~-ray film processors; and
(g) Providing X~~x~~-ray film processing chemicals.
(6) No individual shall perform services that are not specifically stated for that individual on the notice of licensure (certificate of validation or acknowledgment of validation) issued by the Authority.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices ~~Which~~ [SB A1] Containing Radioactive Material

333-102-0300
Issuance of Specific Licenses

(1) Upon a determination that an application meets the requirements of the Act and these rules, the Authority shall~~will~~ issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Authority may incorporate in any license 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 subject to this division as it deems appropriate or necessary in order to:

(a) Minimize danger to public health and safety or property;

(b) Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(c) Prevent loss or~~of~~ theft of material subject to this division.

(3) Whenever the Authority denies an application for a new license or a license renewal, the Authority shall~~will~~ notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to OAR 333-102-0345.

Stat. Auth.: ORS 453.635, 453.665
Stats. Implemented: ORS 453.605 - 453.807

(l) Industrial Radiography:
(A) Fixed Facility, $3,000(F);
(B) Field Use, $3,000(F);
(m) Instrument Calibration, $1,035~~828~~(S);
(n) Investigational New Drug, $2,065~~1,652~~(F);
(o) Irradiator Self-Shielded, $1,370~~1,096~~(S);
(p) Manufacturing/Compounding, $3,000~~2,936~~(F);
(q) Mobile Nuclear Medicine, $3,000~~2,936~~(F);
(r) NORM (no processing), $920~~736~~(F);
(s) Nuclear Pharmacy, $3,000(F);
(t) Other Measuring Device, $200~~160~~(S). Six sources or more, for attenuation purposes, may apply for a basic license;
(u) Portable Gauge:
(A) X-ray Fluorescence, $690~~552~~(S);
(B) All other portable gauges, $920~~736~~(S);
(v) Radiopharmaceutical Therapy, $2,065~~1,652~~(F);
(w) RAM/NOS Facility, $3,000(F);
(x) Research & Development, $2,065~~1,652~~(F);
(y) Sealed Sources for Diagnosis, $690~~552~~(S);
(z) Source Material, $3,000(F);
(aa) Special Nuclear Material (sealed), $1,370~~1,096~~(S);
(bb) Special Nuclear Material (unsealed), $3,000~~2,756~~(F);
(cc) Teletherapy (external beam), $3,000(S);
(dd) Unique, $No Fee;
(ee) Uptake and Dilution, $920~~736~~(F);
(ff) Use of Xenon Gas, $920~~736~~(F);
(gg) Waste Packaging, $3,000(F);
(hh) Well Logging, $2,065~~1,652~~(S);
NOTE: (F) means facility; (S) means source.
(3) Each specific license validation fee shall be due and payable:
(a) ~~Each specific license validation fee shall be due and payable~~ Bbased on the following fee schedule:~~.~~
(A) Validation fees for licenses expiring July through September are due by October 1 each year.
(B) Validation fees for licenses expiring October through December are due by January 1 each year.
(C) Validation fees for licenses expiring January through March are due by April 1 each year; and,
(D) Validation fees for licenses expiring April through June are due by July 1 each year.
(b) For each specific license source of radiation listed in section (2) of this rule for which application pursuant to OAR 333-102-0190 for an Oregon Radioactive Materials License has been made;
(c) For each additional specific license source of radiation in an amendment to an existing Oregon Radioactive Materials License pursuant to OAR 333-102-0320.
(4) A license for each specific license issued pursuant to section (3) of this rule shall be provided by the Authority. The certificate of validation for the current fiscal year shall be retained by the licensee and attached to the license pursuant to requirements in OAR 333-111-0005.

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 103

FEES

333-103-0003
Definitions
As used in this division, the following definitions apply:
(1) "License" ("Acknowledgment of Validation," "Validation Certificate," "Certificate of Validation") means the document issued that validates receipt of payment for a specific license or registration fee.
(2) "Registration Fee" means:
(a) The fee paid to the Authority for registering ~~a license for~~ Radiation Producing Machines; or
(b) The fee paid to the Authority to validate a general license registration issued pursuant to OAR 333-102-0101, 333-102-0103, 333-102-0115, 333-102-0130, or 333-102-0340
(3) "Specific License Fee" means:
(a) The annual fee payable, to validate specific licenses for sources of radiation; or
(b) The fee paid upon application to the Authority for an Oregon Radioactive Materials License to license specific licensed sources of radiation pursuant to OAR 333-103-0010; or
(c) The fee paid to license additional sources of radiation pursuant to OAR 333-103-0010.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0010
Annual Fee for Specific Licenses
(1)(a) Each specific license listed in section (2) of this rule, as defined in OAR 333-102-0203, shall be licensed pursuant to sections (2), (3), (4), (5), and (6) of this rule by a specific license fee.
(b) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the current fiscal year.
(2) Each specific license type appearing in the following fee schedule shall be licensed separately with a specific license fee as indicated:
(a) Analytical/Leak Test/Fixed X-ray Fluorescence, $690~~552~~(F);
(b) Basic License, $1,220~~976~~(F);
(c) Brachytherapy, $2,755~~2,204~~(F);
(d) Broad Scope A, $3,000(F);
(e) Broad Scope B, $2,755~~2,204~~(F);
(f) Broad Scope C, $1,370~~1,096~~(F);
(g) Distribution, $1,370~~1,096~~ (F);
(h) Fixed Gauge, $345~~276~~(S);
(i) High, medium and low doserate brachytherapy, $3,000 ~~2,756~~(S);
(j) Imaging and Localization, $1,370~~1,096~~(F);
(k) In Vitro Laboratory, $455~~364~~(F);

(5) The specific license fee that validates specific sealed sources also validates possession of one additional sealed source during source exchange (one new source and one spent source) for a period not to exceed 30 calendar days.
(6) Sealed sources manufactured and distributed as reference sources that do not exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 are exempt from specific license fees and validation if used pursuant to a specific license listed in section (2) of this rule. The license validation fee for reference sources that exceed 100 times the quantity in 30.71 Schedule B of 10 CFR Part 30 or reference sources authorized alone without additional licensed radioactive material shall be $1,220~~976~~, pursuant to subsection (2)(b) of this rule.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0015
Annual Registration Fee for General Licenses and Devices
(1) Any general license granted by the Authority must be validated annually by the general license registration fee listed in section (2) of this rule, unless otherwise exempted by subsection (2)(c) of this rule. Validation must be confirmed by verifying, correcting, and~~/or~~ [ANN1] adding to the information provided in a request for registration received from the Authority. General License registration fees as defined in OAR 333-103-0003 shall:
(a) Validate each general licensed source of radiation due October 1 of each year for sources of radiation; and
(b) Validate each new application to register general license material pursuant to OAR 333-101-0007; and
~~(c) Registration.~~ [ANN2]
(2) The general licenses appearing in the following fee schedule shall be registered on the appropriate Authority form and shall be validated annually by a general license registration fee:
(a) Each healing arts facility that uses radioactive material for In Vitro laboratory or clinical testing authorized by OAR 333-102-0130, $200~~160~~;
(b) Each radiation source in a generally licensed measuring, gauging or controlling device authorized pursuant to OAR 333-102-0115(1), $200~~160~~;
(c) For radioactive material contained in devices designed and manufactured for the purpose of producing light, except Tritium exit signs, or an ionized atmosphere that exceed the limits in OAR 333-102-0105, $82~~66~~ per device for the first 12~~twelve~~ devices after which a Basic Specific License is required.
(d) Each general licensee possessing or using depleted uranium for the purpose of providing a concentrated mass in a small volume of the product or device pursuant to OAR 333-102-0103, $200~~160~~;
(e) Each General Licensee possessing or using source material for research, development, educational, commercial or operational purpose~~d~~ pursuant to OAR 333-102-0101, $300~~240~~;
(f) General licenses not specifically identified in subsections (2)(a), (2)(b), (2)(c) and (2)(d) of this rule are exempt from the payment of an annual general license registration fee.
(g) Each out-of-state or NRC specific licensee granted a general license pursuant to OAR 333-102-0340 to conduct activities within the State of Oregon for a period not to exceed 180 consecutive days in a calendar year must pay a registration validation fee as required by OAR 333-103-0030(16).

(h) State and local government agencies are required to register each generally licensed device but are exempt from the fees required in this rule.
(3) Notwithstanding subsection (2)(g) of this rule, the general license fee shall be due and payable on or before October 1 of each year.
(4) A certificate of validation for the then current fiscal year shall be provided by the Authority. The certificate for the then current fiscal year must be retained by the licensee and attached to the general license.
(5) Upon written request and approval by the Authority, fees for new licenses or additional sources may be prorated on a quarterly basis for the fiscal year.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0030
Reciprocal Recognition Fee
(1) Any radiation machine or radioactive material source brought into the state for use under reciprocity must pay a fee equal to 100 percent of the appropriate license or registration validation fee, listed in OAR 333-103-0005 or 333-103-0010, not to exceed $3,000 in a year.
(2) Reciprocal fees shall be due and payable prior to entry into the state.
(3) An acknowledgment of fee payment, such as a certificate of validation, shall~~will~~ be provided by the Authority. The acknowledgment of fee payment must be retained by the licensee or registrant and attached to the license or registration.
(4) Reciprocal fees shall not be transferred or refunded.
(5) Reciprocal fees shall expire ~~twelve12~~ [o3] months from the issue date.
(6) Any use of radioactive material in Oregon pursuant to OAR 333-102-0340 exceeding 180~~30~~ consecutive days ~~or 180 calendar days shall~~ may be required ~~an application for~~ to apply for an Oregon specific radioactive materials license pursuant to OAR 333-102-0190.
Stat. Auth.: ORS 453.757
Stats. Implemented: ORS 453.757

333-103-0035
Fees ~~f~~For Radiological Analyses
(1) An individual, agency, or company that requests that the Authority's [SBA4]Radiation Laboratory perform radiological analyses on samples must pay a fee to the Authority in accordance with the schedule in section (2) of this rule. The responsible individual submitting the sample(s) must first obtain a request form from the Authority. This form contains the fee schedule and the types of radiological analyses offered. That individual must then submit the completed form along with the sample and the appropriate fee to the Authority. The Authority submits must~~will~~ send [o5] the results by return mail in accordance with the estimated time as per section (3) of this rule.
(2) Fee Schedule:
(a) Gamma Isotopic:
(A) Liquid — $310~~248~~;
(B) Solid — $355~~284~~;
(b) Low-level Iodine-131 — $265~~212~~;
(C) Tritium (H-3) — $115~~92~~.

(3) The analyses results shall~~will~~ be available in approximately five working days for Gamma Isotopic analyses.

NOTE: If the Authority cannot complete the analyses according to the schedule in section (3) of this rule, the Authority must~~will~~ notify the customer as soon as possible.

(4) A $100 surcharge shall be added to the fee for a one-day completion schedule for a Gamma Isotopic analysis.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Underlined text is being added. ~~Strikethrough text~~ is being deleted.

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 106

X-RAYS IN THE HEALING ARTS

General Requirements

333-106-0015
Technique Chart

A useable up-to-date chart shall be provided in the vicinity of the diagnostic X~~x~~-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(1) Patient's anatomical size in centimeters versus technique factors to be utilized.

(a) For v~~V~~eterinary X-rays, the patient's anatomical size in centimeters or weight in pounds versus technique factors to be used.

(2) Film-screen combination to be used.

(3) Type and focal distance of the grid to be used, if any.

(4) Source to image receptor distance to be used.

(5) Indication of radiographic examinations requiring gonad shielding, except in the case of veterinary use.

(6) Units utilizing phototimers shall have a chart indicating cell choice, optimum kVp and density setting as well as other applicable requirements of this rule.

(7) Units utilizing automatic techniques that are incorporated in the X-ray machine are considered to meet the requirements of sections (1), (2), (3) and (4) of this rule.

(8) In cases where machine use is restricted to intraoral radiography, or one operator and less than three techniques, the registrant is exempt from the requirements of this rule.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0055
X-ray Operator Training

(1) The registrant shall assure that individuals ~~who will be~~ operating the X-ray equipment ~~shall~~ have adequate training in radiation safety. Adequate training in radiation safety means a minimum of 40 hours of didactic instruction for diagnostic medical X-ray equipment operators, eight hours for Grenz ray X-ray equipment operators and 20 hours for veterinary X-ray equipment operators from an Authority approved training course covering the following subjects:

(a) Nature of X-rays;
(b) Interaction of X-rays with matter;
(c) Radiation units;
(d) Principles of the X-ray machine;
(e) Biological effects of X-ray;
(f) Principles of radiation protection;

(g) Low dose techniques;
(h) Applicable federal and state radiation regulations including those portions of divisions 100, 101, 103, 106, 111 and 120 of chapter 333;
(i) Darkroom and film processing;
(j) Film critique; and
(k) Animal restraint training (for veterinary technologists or assistants only).
NOTE: Subsections (1)(g), (1)(i), (1)(j) and (1)(k) of this rule are not required for Grenz ray X-ray equipment operator training.
(2) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:
(a) Currently licensed by the Oregon Board of Dentistry as a dDentist or dDental hHygienist; or
(b) Is a dDental aAssistant who is certified by the Oregon Board of Dentistry in radiologic proficiency; and
(c) Successfully completed didactic and clinical radiography training covering the subject areas outlined in section (1) of this rule; and
(d) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered by the Dental Assisting National Board, Inc. (DANB) and clinical radiography examination or other comparable requirements approved by the Oregon Board of Dentistry.
(3) Medical X-ray equipment operators not regulated by the Oregon Board of Medical Imaging. In addition to the above, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of X-ray examinations that the individual ~~will~~ may be performing; and
(a) Have 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer; and
(b) Must have completed the required radiation use and safety hours and a minimum of 50 hours in X-ray laboratory before X-raying a human patient.
(4) Radiation Use and Safety Instructor Qualifications. The training required in sections (1), (2) and (3) of this rule must be taught by an Authority approved instructor. Approval ~~will~~ shall be based upon the following criteria:
(a) Medical use and safety instructor: An individual who is currently licensed as a rRadiologic tTechnologist [SBAI]and approved as an education provider by the Oregon Board of Medical Imaging.
(b) A dental radiation use and safety instructor is an individual who has:
(A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered DANB; or
(B) Has been evaluated and approved as a qualified dDental radiation use and safety instructor by the Oregon Board of Dentistry; and
(C) Is currently licensed by the Oregon Board of Dentistry as a dentist; or
(D) Is a dental hygienist; or

(E) Is a dental assistant certified in r~~R~~adiologic proficiency and has a minimum of two years of experience in taking dental radiographs.
(c) A veterinarian radiation use and safety instructor is an individual who ~~is~~:
(A) Is c~~C~~urrently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a r~~R~~adiologic t~~T~~echnologist [SBA2]by the Oregon Board of Medical Imaging; and
(B) Has completed training specific to veterinarian radiography, including training in animal restraint; and
(C) Has~~ve~~ a minimum of two years of experience in taking veterinary radiographs.
(d)~~(A)~~ On a case by case basis, if an evaluation by the Authority reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (4)(a), (4)(b) or (4)(c) of this rule; or
(A) I~~i~~s an individual who is qualified under OAR 333-101-0230 as a Hospital Radiology Inspector; or
(B) The individual meets the requirements of a qualified expert as defined in OAR 333-101~~0~~-0005(80).
(5) In addition to the requirements in sections (2), (9), (10) and (13), of this rule the dental X-ray equipment operator must also satisfy any requirements established by the Oregon Board of Dentistry.
(6) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.
(7) Any diagnostic medical X-ray operator is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:
(a) Holds a current license from the Oregon Board of Medical Imaging; or
(b) Holds a current limited permit from the Oregon Board of Medical Imaging; or
(c) Is a student in a two-year approved school of r~~R~~adiologic t~~T~~echnology [SBA3]as defined in ORS 688.405 while practicing r~~R~~adiologic t~~T~~echnology under the supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Medical Imaging; or
(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a r~~R~~adiologic t~~T~~echnologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Medical Imaging.
(8) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect supervision of a d~~D~~entist or d~~D~~ental h~~H~~ygienist currently licensed or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry provided that:
(a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or
(b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and
(c) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (1) of this rule; and
(d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:

(A) The use of mannequins under indirect supervision; or
(B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and
(C) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site(s) of their clinical training and available for review by the Oregon Health Authority, Public Health Division inspection staff at the time of inspection.
(9) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 ~~of these rules~~.
(10) The students identified in section (8) of this rule are considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of 12 consecutive months.
(11) Radiation use and safety training programs approved prior to ~~the~~ May 1, 2005 ~~will~~ shall continue to be considered as meeting the requirements of section (1) of this rule provided they cover those portions of the Oregon Rules for the Control of Radiation indicated in subsection (1)(h) of this rule.
(12) X-ray operator training approved prior to May 1, 2005 shall~~will~~ continue to be considered as having met the requirements of sections (1), (2) or (3) of this rule as applicable.
(13) Reciprocity. X-ray equipment operators who have received their radiation safety training outside of Oregon shall~~will~~ be considered to have met the training requirements listed in sections (1) or (2) of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of sections (1) or (2) of this rule.
(14) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.
(a) Records of this training must be maintained by the registrant for inspection.
(b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

Radiographic Systems other than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography X-ray Systems

333-106-0325
Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101, the requirements of this rule apply to X-ray equipment and facilities where intraoral dental radiography is conducted. Requirements for extraoral dental radiographic systems are covered in OAR 333-106-0301 through 333-106-0320. Intraoral dental radiographic systems must meet the following requirements:

(1) Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than 18cm.~~:~~

~~(a) 18 cm if operable above 50 kVp; or~~

~~(b) 10 cm if operable at 50 kVp only.~~

(2) Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or

(b) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

(3) Radiation Exposure Control (Timers). Means shall be provided to control the radiation exposure through the adjustment of exposure time in seconds, milliseconds (ms) or, number of pulses, or current/milliamps (mA), or the product of current and exposure time (mAs) or adjustment of kVp. In addition:

(a) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

(b) It shall not be possible to make an exposure when the timer is set to a "0" or "off" position if either position is provided;

(c) Exposure Indication. Means shall be provided for visual indication, observable at or from the operator's protected position, whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

~~(d) Exposure termination[O4]. [SBA5]~~

(de) Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (Tmax) minus the minimum exposure time (Tmin) when four timer tests are performed: (T) >5 (Tmax – Tmin).

(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.

(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".

(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:

(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(80), and the operator shall remain in that protected area during the entire exposure; and

(b) The operator's protected area shall provide visual indication of the patient during the X-ray procedure.

(c) Mobile and portable X-ray systems which are:

(A) Used for greater than one week in the same location such as ~~, i.e., ,~~[SBA6]a room or suite, shall meet the requirements of subsections (4)(a) and (4)(b) of this rule.

(B) Used for less than one week at the same location, such as ~~i.e.,~~ [SBA7]a room or suite, shall be provided with:
(i) Either a protective barrier of at least 6.5 feet (2 meters) high for operator protection; or
(ii) A means to allow the operator to be at least nine feet (2.7 meters) from the tube housing assembly while making exposures; or
(iii) A full length protective apron, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand-held dental intraoral X-ray machine.
(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E >5 (Emax - Emin)
(6) Accuracy.
(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.
(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 55~~0~~ kVp shall not be used to make diagnostic dental radiographs on humans.
(7) Administrative Controls.~~:~~
(a) Patient and film holding devices shall be used when the techniques permit;
(b) The tube housing and the PID shall not be hand held during an exposure;
(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection (2)(a) of this rule or its updated version;
(d) All patients shall be provided with a leaded apron during any dental X-ray exposure;
(e) Dental fluoroscopy without image intensification shall not be used;
(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Authority.
(8) Hand-held X-ray systems.
(a) Registrants must provide for security and safe storage while not in use.
(A) A report must be filed with the Authority within 72 hours if the hand-held unit is lost or stolen.
(b) The image receptor used with hand-held dental X-ray systems must either be:
(A) A speed class of intra-oral film designated as "~~"~~E/F"~~"~~, "~~"~~F"~~"~~ or faster; or
(B) A digitally acquired image (CR or DR).
(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.
(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand-held unit must provide documentation to the Authority of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.
(c) The hand-held unit must be capable of a minimum of 60 kVp and 2.0 mA.
(f) Hand-held units not meeting the requirements of subsections (8)(c), (8)(d) and (8)(c) of this rule may not be sold, distributed or used in the State of Oregon.
(9) Hand-held dental X-ray administrative controls.

(1) "Annual" means a period of 12 consecutive months, not to exceed a period of 14 months.
(2) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X~~x~~-ray transmission data. Computed tomography includes the capability of producing axial tomograms.
~~(3) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT hybrid scanners if used for diagnostic CT procedures[ML18].~~
(3~~4~~) "Computed Tomography Dose Index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan. This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.
(4) "Contrast scale" or "CS" means the change in the linear attenuation coefficient per CTN relative to water.
~~(5) "CS" (see Contrast scale).~~
(5~~6~~) "CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in OAR 333-106-0005.
(6~~7~~) "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.
(7~~8~~) "CT n~~N~~umber" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.
(~~3~~8~~9~~) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT hybrid scanners if used for diagnostic CT procedures.
~~(52) "Contrast Scale" means the change in the linear attenuation coefficient per CTN relative to water.~~
~~(63) "CS" (see Contrast scale).~~
~~(74) "CT Conditions of Operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in OAR 333-106-0005.~~
(9~~1085~~) "$CTDI_{vol}$" (see c~~C~~omputed tomography dose index).
~~(96) "CT Gantry" means the tube housing assemblies, beam limiting devices, detectors, and the supporting structures and frames which hold these components.~~
(10~~107~~) CTN (see CT number).
~~(118) CT Number means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.~~
(11~~2~~) "Dose-length product (DLP)" is the $CTDI_{vol}$ multiplied by the scan length (image thickness multiplied by the number of adjacent, non-overlapped images in the acquisition in centimeters.
(12~~39~~) "Dose p~~P~~rofile" means the dose as a function of position along a line.
(13~~40~~) "Elemental a~~A~~rea" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also p~~P~~icture element.)

(a) The operator must wear a whole body protective apron and thyroid collar of 0.25 mm of lead equivalent when using the unit.
(b) Hand-held units must meet the requirement of OAR 333-106-0045(3).
(A) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.
(B) The unit can only be operated in an enclosed room when possible. All individuals except the X-ray operator and the patient must leave the room and stand behind a protective barrier or be at least six feet from the X-ray source if a protective barrier is not available during radiographic exposures.
(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(14) before using a hand-held unit.
(A) Training on the safe use of the unit shall be documented and include at a minimum:
(i) Proper positioning of the unit to ensure an adequate protected position;
(ii) Limitations on the use of position indicating devices that require longer distances to the patient's face;
(iii) Diagrams ~~(i.e.~~ such as drawings, illustrations, or schematics, ~~etc.)~~ [SBA8]of protected position and location in relationship to the unit;
(iv) Diagrams (such as~~i.e.,~~ drawings, illustrations, or schematics, ~~etc.)~~ of the effect of improper distance or removal of shielding device; and
(v) Diagrams such as ~~(i.e.~~ drawings, illustrations, schematics,~~etc.)~~ of common examples of improper positioning of the unit and or location of the operator.
(d) An appropriate receptor holder must be used during the X-ray exposure.
(e) A PID must be used during the X-ray exposure.
(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

~~[CH9]S[O10][SBA11][SBA12][ANN13]~~

Computed Tomography X-ray Systems

333-106-0345
Purpose and Scope
(1) OAR 333-106-0350 through OAR 333-106-0369 establishes requirements governing the use of computed tomography (CT) scanners in the healing arts; and
(2) Applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.
~~(1[O14][ML15]) In addition to the requirements of this part, all registrants are subject to chapter 333, divisions 100-124 as appropriate.~~[ANN16]

333-106-0350
Definitions
In addition to the definitions provided in division 100 and 106 of these rules, the following definitions shall be applicable to OAR 333-106-0350 through OAR 333-106-0369 ~~this rule~~[SBA17].

(14~~54~~) "Multiple t~~T~~omogram s~~S~~ystem" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.
(15~~65~~2) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.
(16~~76~~3) "Nominal t~~T~~omographic s~~S~~ection t~~T~~hickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.
(17~~8~~) "Picture e~~E~~lement" means an elemental area of a tomogram.
(18~~97~~) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.
~~(184) "Picture Element" means an elemental area of a tomogram.~~
(19~~2019~~) "Qualified CT m~~M~~edical p~~P~~hysicist" means an individual qualified in accordance with OAR 333-106-0367.
(20~~1015~~) "Reference p~~P~~lane" means a plane which is displaced from and parallel to the tomographic plane.
(21~~2116~~) "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.
(22~~3217~~) "Scan i~~I~~ncrement" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.
(23~~4318~~) "Scan s~~S~~equence" means a ~~preselected set of two or more scans performed consecutively under~~ preselected set of two or more scans performed consecutively under preselected CT conditions of operation.
(24~~5419~~) "Scan t~~T~~ime" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.
(25~~65~~) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimensional images of functional processes in the body.
(26~~760~~) "Single Tomogram System" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.
(27~~87~~) "Tomogram" means the depiction of the attenuation properties of a section through a body.
(28~~981~~) "Tomographic p~~P~~lane" means that geometric plane which is identified as corresponding to the output tomogram.
(29~~3029~~2) "Tomographic s~~S~~ection" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.
(30~~10~~) "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every two2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus [SBA19]three percent~~3%~~ of the national standard in the appropriate energy range.

Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0355
CT Equipment Rrequirements
(1) CT c~~E~~quipment requirements shall comply with the Food and Drugs Administration's 21 CFR in the following areas:
(a) Information to be provided for users – Part 1020.33(c);~~.~~
(b) Quality Assurance – Part 1020.33(d);~~.~~
(c) Control and indication of conditions of operation – Part 1020.33(f);~~.~~
(d) Tomographic plane indication and alignment - Part 1020.33(g);~~.~~
(e) Beam-on and status indicators – Part 1020.33(h);~~.~~
(f) Scan increment accuracy – Part 1020.33(i); and ~~.~~
(g) CT number mean and standard deviation – Part 1020.33(j).
~~(1) Termination of Exposure:~~
~~(a) Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function;~~
~~(b) A visible signal shall indicate when the X-ray exposure has been terminated through the means required by subsection (1)(a) of this rule;~~
~~(c) The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.~~
(2) CT equipment shall be maintained in compliance with the requirements of section (1) of this rule.
~~(2) Tomographic Plane Indication and Alignment:~~
~~(a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane;~~
~~(b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes;~~
~~(c) If a device using a light source is used to satisfy subsection (2)(a) or (b) of this rule, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.~~
~~(3) Beam-On and Shutter Status Indicators and Control Switches:~~
~~(a) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed;~~
~~(b) Each emergency button or switch shall be clearly labeled as to its function.~~
~~(4) Indication of CT Conditions of Operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operations at fixed values, this requirement may be met by~~

~~permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.~~
~~(5) Extraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by OAR 333-106-0101(5) of these rules.~~
~~(6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.~~
~~(7) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985:~~
~~(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters;~~
~~(b) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible;~~
~~(c) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel;~~
~~(d) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.~~
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0360
Facility Design Requirements
(1) ~~)~~A fixed CT scanner room shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations. ~~Aural Communication. Provisions shall be made for two-way aural communication between the patient and the operator at the control panel.~~
(2) The CT scanner shall be situated in a protected area and is subject to design approval by a qualified expert. National Council on Radiation Protection and measurements (NCRP) Report #147 shall be used as guidance for determining adequate shielding. ~~Viewing Systems:~~
~~(a) Windows, mirrors, closed-circuit televisions, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel;~~
~~(1)~~ ~~(b) When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.~~
(3) The control panel for a fixed CT scanner shall be in a protected area.
(4) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with section (3) of this rule.

(5) The operator of a fixed CT scanner shall be able to see and communicate with the patient from the protective area at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.
(6) Mobile or portable CT scanners used routinely in one~~l~~ location shall be considered a fixed installation and shall comply with the requirements of sections (1) throughe (5) of this rule.
(7) CT scanners mounted in a vehicle or trailer must meet requirements of sections (1) through ~~–~~(5) of this rule..
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.775

333-106-0361
Radiation Protection Surveys
(1) The registrant must ensure that radiation protection surveys are performed at new facilities, at existing facilities not previously surveyed, and anytime the CT scanner is replaced, moved or structural changes are made in the room.
(2) In new facilities, a radiation protection survey must be completed prior to the first clinical use following installation.
(3) The radiation protection survey must be performed by a qualified CT medical physicist [SBA20]as defined in 333-106-0367) or a qualified expert [SBA21]as defined in 333-100-0005.
(4) Surveys must be conducted with an operable radiation survey instrument that has been calibrated according to manufacturer's specifications, not to exceed 24 months. If manufacturer specifications are not available, then the radiation survey instrument shall be calibrated every 12 months.
(5) The Qualified CT Medical Physicist or Qualified Expert must verify that:
(a) Radiation levels in restricted areas are not likely to cause personnel to receive exposures in excess of the limits specified in OAR 333-120-0100(1); and
(b) Radiation levels in unrestricted areas do not exceed the limits specified in OAR 333-120-0180 and 333-120-0190.
(6) The radiation protection survey record must be documented and indicate all instances where the facility, in the opinion of the Qualified Medical Physicist or ~~a~~Qualified Expert, is in violation of applicable regulations. The survey record must also include the:
(a) Date of the measurements;
(b) Reason the survey is required;
(c) Manufacturer's name, model number and serial number of the CT scanner;
(d) Manufacturer's name, ~~and~~ model number and serial number of the instrument(s) used to measure radiation levels and the date last calibrated;
(e) F~~A~~ floor plan of the areas surrounding the exam room that were surveyed;
(f) Measured dose rate at several points in each area expressed in mSv/hr or mR/hr~~.~~;
(g) Calculated maximum level of radiation over a period of one~~l~~ week for each restricted and unrestricted area;
(h) Signature of the individual responsible for conducting the survey; and
(i) The survey must be available for review at the time of inspection.
Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: [ANN22] ORS 453.605 - 453.807

333-106-0362
Operating Procedures and Conditions of Operation
(1) Within six months following the effective date of these rules, the CT facility shall establish default scanning protocols in consultation with a qualified CT medical physicist.[SBA23]
(2) Default scanning protocols shall be ~~either~~ password protected or a written policy shall be in place that prohibits anyone from changing protocols without documented approval from the CT medical director, lead CT technologist or supervising CT rRadiologist.
(a) Each facility shall establish a policy to review all of their ~~CT~~ default CT protocols at least annually to ensure they are correct and are the intended protocols.
(b) Written and signed documentation of this annual review shall be kept and made available for inspection for each CT unit at the facility.
(3) The CT operator shall ensure all technique factors and dose indices are appropriate for the protocol being used and the patient being imaged. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors.
(4) The facility shall establish a written policy for retaking CT exams on patients.
(5) Staff shall not be required by the licensee or registrant to hold patients during CT examinations.
(6) When a patient must be held in position for a CT procedure, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body shall ~~will~~ be in the path of the primary beam and that his or her body is as far as possible from the edge of the primary beam.
(7) Only individuals whose presence is necessary are allowed in a CT scan room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.
(8) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which must ~~will~~ prevent use of the apparatus by unauthorized persons.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807[ANN24]

333-106-0363
Quality Control Program
(1) The registrant shall ensure that a CT quality assurance phantom is available for testing the CT system.
(2) Instructions on the use of the phantom shall be provided. The instructions shall include a schedule of tests appropriate for the CT system, the allowable variations for the test parameters~~.~~, and a method to store the test results.
(3) Within six months following the effective date of these rules, a CT facility shall establish and implement a quality control program under the ~~supervision~~direction of a CT medical physicist[O25]. [SBA26]

(4) Evaluations and tests shall be performed following written procedures and methods.
(5) Corrective action shall be taken and documented according to instructions provided by the qualified CT medical physicist [SBA27]if the results of an evaluation or test fall outside the control limits.
(6~~5~~) The qualified CT medical physicist shall determine the frequency of each test. An on-site CT Radiologic Technologist shall be identified to be responsible for the ongoing quality control testing.
(7~~6~~) The ongoing quality control evaluation must ~~should~~ include, at a minimum, the following:
(a) Water CT number accuracy check and standard deviation (n~~N~~oise);
(b) Artifact evaluation;
(c) Visual checklist; and
(d) Printer quality control (if used for primary interpretation).
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807 [ANN28]

333-106-0364
Initial and Annual Qualified CT Medical Physicist Scanner Performance Evaluations
(1) A CT medical physicist shall complete an initial performance evaluation of the CT scanner before use on patients and annually thereafter.
(2) Surveys~~A~~ performance evaluation of the CT system shall be performed after any change in the ~~facility or~~ equipment which might cause a change in the radiation output~~n increase in radiation exposure~~ or ~~any changes in the image quality of the~~ images quality.
(3) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months, or per manufacturer's specifications, and shall be traceable to a national standard.
(4) A performance evaluation shall include the following, as a minimum:
(a) Alignment light accuracy;
(b) Alignment of table to gantry;~~,~~
(c) Gantry tilt, as appropriate;
(d) Slice localization from scanned projection radiograph;~~,~~
(e) Table travel accuracy;~~,~~
(f) Image thickness;
(g) Radiation b~~B~~eam w~~W~~idth;
(h) Image quality, including the following:
(A) Gray level performance of CT a~~A~~cquisition display monitors,~~;~~
(B) Low-contrast performance,~~;~~
(C) Image uniformity,~~;~~
(D) Noise,~~;~~
(E) Artifact evaluation,~~;~~ and
(F) Spatial r~~R~~esolution;
(i) CT number uniformity;
(j) Dosimetry, including the following:
(A) Dose indicator such as computed tomography dose index ($CTDI_{vol}$),~~;~~ and
(B) Patient radiation dose for representative examinations.~~,~~

(k) A ~~S~~safety evaluation, including the following:
(A) Visual inspection,~~.~~
(B) Audible and visual signals~~:~~, and
(C) Posting requirements.~~.~~
(~~l~~l) A ~~R~~review of clinical protocols that~~-~~shall include at a minimum:
(A~~A~~) An evaluation of scanner features, including kV, mAs, detector configuration, reconstructed scan width, pitch, reconstruction algorithm, and other features such as dose reduction options, including automatic exposure controls, iterative reconstruction techniques, etc. to ensure they are being properly utilized; and
(B~~B~~) A r~~R~~eview of the following clinical protocols, if they are used on the CT scanner:~~:~~
(i~~i~~) Pediatric head (one~~l~~ year old);~~.~~
(iii~~i~~) Pediatric abdomen (five~~5~~ years old; 40-50 pounds~~lb~~ or approximately~~.~~ 20 kilograms~~g~~);~~.~~
(iiii~~i~~i) Adult head;~~.~~
(iv~~i~~v) Adult abdomen (70 kilograms~~g~~);~~.~~
(v~~v~~) High-r~~R~~esolution chest;~~.~~
(vi~~v~~i) Brain perfusion;~~.~~ and
(vii~~v~~ii) Low dose lung cancer screening exam.
~~(m) The CTDI for the following CT examinations on standard phantoms shall not exceed the dose limits listed below:~~

~~(A) Adult Head, 80 mGy~~

~~(B) Adult Abdomen, 30 mGy~~

~~(C) Pediatric Abdomen (5 years of age or 40 lbs.), 20 mGy~~

~~(D) Pediatric Head, 40 mGy~~
[CH29]
(m~~n~~) A ~~R~~review of the facility's ongoing quality control program, including test results and corrective action.
(5~~o~~) Evaluations and tests shall be performed following written procedures and methods found in the latest ACR CT Quality Control Manual.
6~~5~~) The qualified ~~Expert~~CT medical p~~P~~hysicist shall prepare a report ~~must~~that includes the following:
(a) A summary of the performance evaluation required under section (1) of this rule;~~.~~
(b) Recommendations for necessary improvements;~~.~~ and
(c) The ~~T~~type of dosimetry system used, including the date of the last calibration.~~.~~
(7~~6~~) The report required under section (~~5~~6) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation and shall be made available to the Authority upon request.~~.~~
(8~~7~~) The facility shall keep written documentation of actions taken ~~to~~in response to the recommend~~ed ite~~mations from the ~~survey~~performance evaluation report.
(9~~8~~) Records of preventive maintenance and repair shall be retained for each CT scanner and be made available to the Authority upon request.
Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807[ANN30]

~~333-106-0365~~
~~Surveys, Calibrations, Spot Checks, and Operating Procedures~~
~~(1) Surveys:~~
~~(a) All CT X-ray systems installed after December 1990 and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard;~~
~~(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Authority upon request.~~
~~(2) Radiation Calibrations:~~
~~(a) The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;~~
~~(b) The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output;~~
~~(c) The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years;~~
~~(d) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:~~
~~(A) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 +- 0.01 grams per cubic cm or a reasonable substitute. The phantom(s) shall be at least 14 cm in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;~~
~~(B) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;~~
~~(C) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;~~
~~(D) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.~~
~~(3) The calibration shall be required for each type of head, body, or whole body scan performed at the facility.~~
~~(4) Calibration shall meet the following requirements:~~
~~(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by~~

~~the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;~~
~~(b) The CTDI along the two axes specified in paragraph (2)(d)(B) of this rule shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.~~
NOTE: ~~For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.~~
~~(c) The spot checks specified in section (5) of this rule shall be made;~~
~~(d) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Authority.~~
~~(5) Spot Checks:~~
~~(a) The spot check procedures shall be in writing and shall have been developed by a qualified expert;~~
~~(b) The spot check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material;~~
~~(c) Spot checks shall be included in the calibration required by section (2) of this rule and at time intervals and under system conditions specified by a qualified expert;~~
~~(d) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operations as are used to perform calibrations required by section (2) of this rule. The images shall be retained, until a new calibration is performed, in two forms as follows:~~
~~(A) Photographic copies of the images obtained from the image display device; and~~
~~(B) Images stored in digital form on a storage medium compatible with the CT X-ray system.~~
~~(e) Written records of the spot checks performed shall be maintained for inspection by the Authority.~~
~~(6) Operating Procedures:~~
~~(a) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation;~~
~~(b) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:~~
~~(A) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;~~
~~(B) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variation for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;~~
~~(C) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and~~
~~(D) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.~~

~~(7) If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.~~
~~Stat. Auth.: ORS 453.605 - 453.807~~
~~Stats. Implemented: ORS 453.605 - 453.807~~
~~Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08~~

333-106-0366
Dose Limits
(1) The $CTDI_{vol}$ for the following CT examinations on standard phantoms shall not exceed the dose limits listed below:
(a) Adult head, 80 mGy;
(b) Adult abdomen, 30 mGy;
(c) Pediatric abdomen (five~~5~~ years of age or 40 pounds~~lbs.~~), 20 mGy; and
(d) Pediatric head, 40 mGy.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807 [ANN31]

333-106-0367
Records and Report Retention
(1) A facility with a CT scanner shall maintain records and reports on file and shall make the records and reports available for review by the Authority[SBA32] as follows:
(a) Records documenting the qualifications of all personnel who worked at the facility as an operator or CT medical physicist[SBA33].
(b) Records of personnel no longer employed by the facility shall be kept on file until the next inspection following the employee's termination has been completed and the Agency has determined that the facility is in compliance with the CT personnel requirements.
(cb) A report of a CT medical event required under OAR 333-106-0368[ML34] shall be maintained on file for at least seven~~7~~ years.
(dc) Initial and annual CT Medical Physicist performance evaluation reports required under OAR 333-106-0364 shall be maintained on file for at least five~~5~~ years.
(e~~d~~) Records of the results from the ongoing quality control evaluation required under OAR 333-106-0363 shall be maintained on file for at least three~~3~~ years.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807 [ANN35]

333-106-0368
Qualified CT Medical Physicist
(1) In order to perform a CT survey or provide consultative services on a CT unit, a person must be approved by the Authority, under the provisions of OAR 333-101-0020, as a provider of radiation services in CT. ~~-~~In addition, the~~y~~ q~~Q~~ualified CT m~~M~~edical p~~P~~hysicist [SBA36]~~must qualify as a CT medical physicist by f~~shall meet the ~~ollowing the~~ requirements outlined below:

(a) Initial qualifications. Before beginning to ~~independently~~ provide consultation to a CT facility, a medical physicist shall meet one of the following:
(A) Be certified in diagnostic radiological physics or radiological physics by the American Board of Radiology, or in diagnostic imaging physics by the American Board of Medical Physics, or in diagnostic radiology physics by the Canadian College of Physicists in Medicine; or
(B) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least one~~1~~ course in biology or radiation biology and one~~1~~ course in anatomy, physiology, or similar topics related to the practice of medical physics, and have three~~3~~ years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the USA; or
(C) CT medical p~~p~~hysicists who, prior to August 1, 2014, have been actively working in the area of CT in the S~~s~~tate of Oregon and are specifically approved by the Authority to provide CT medical physics services in Oregon, are exempt from the requirements in paragraphs (A) and (B) [SBA37] this rule.
(b) Continuing experience. After the second anniversary of the date when the requirements of ~~subdivision~~subsection (1)(a) of this rule were completed, the medical physicist shall have evaluated at least two~~2~~ CT scanners in the prior 24-month period.
(c) Continuing education. After the third anniversary of the date when the requirements of subsections~~subdivision~~ (1)(a) of this rule were completed, the CT medical physicist shall have earned at least 15 continuing medical education units; at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.
(d) Re-establishing qualifications. A CT medical physicist [ANN38]who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:
(A) A CT medical physicist who fails to meet the continuing experience requirements of ~~subdivision~~subsection (1)(c) of this rule shall evaluate two CT scanners under the supervision of a Medical physicist, to meet the requirements of ~~subdivision~~subsection (1)(c) of this rule.
(B) A CT medical physicist who fails to meet the continuing education requirements of ~~subdivision~~subsection (1)(d) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of ~~subdivision~~subsection (1)(d) of this rule.
(e) Documentation of continuing education and continuing experience shall be kept on file and made available to an inspector upon request.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented ORS 453.605 - 453.807[ANN39]:

333-106-0369
Report and Notification of a CT Medical Event
(1) A CT facility shall notify the Authority[SBA40] within 48 hours of any CT medical event in which a patient who has undergone a CT study has incurred a deterministic radiation injury, such as epilation or erythema.
(2) The registrant shall submit a written report to the Authority within 30 days after the CT medical event is discovered.
(3) The written report shall include all of the following:
(a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate;~~.~~
(b) The name of the individual who determined a CT medical event occurred;~~.~~
(c) The dates of occurrence and discovery of the CT medical event;~~.~~
(d) A narrative description of the CT medical event, including an estimated dose to the patient, if possible, and body part involved;~~.~~
(e) The cause of the CT medical event;~~.~~
(f) The effect on the individual who received the exposure;~~.~~
(g) A narrative detailing corrective action taken or planned to prevent a recurrence;~~.~~
(h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not; and~~.~~
(i) The name and signature of the person preparing the report.
(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.
(5) The registrant shall consult with the referring physician prior to notifying the individual that they were involved in a CT medical event.
(a~~A~~) The registrant shall ensure that the individual was notified of the CT medical event no later than one~~1~~ week after the discovery unless unforeseen circumstances exist.
(b~~B~~) The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event.~~.~~
(c~~C~~) If verbal notification is necessary, the registrant shall inform the individual or legal guardian that a written description of the CT medical event can be obtained from the registrant.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807[ANN41]

Underlined text is being added. ~~Strikethrough text~~ is being deleted.

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

333-116-0045
Provisions for Research Involving Human Subjects.
(1) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified in, and for the uses authorized by its license. ~~authorized by the Authority. This applies whether or not the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy). In addition, the licensee must, before conducting research:~~
(2) ~~(a)~~ ~~Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and~~ If the research is conducted, funded, supported, or regulated by a ~~f~~Federal[SBA1] agency that has implemented the Federal Policy for the Protection of Human Ssubjects (Federal Policy), the licensee shall, before conducting research:
(a) Obtain review and approval of the research from an "Institutional Review Board,"[SBA2] as defined and described in the Federal Policy; and
(b) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.
(3~~2~~) ~~Nothing in this rule relieves a licensee from complying with the other requirements in this part.~~ If the research is ~~will~~not ~~be~~ conducted, funded, supported, or regulated by another ~~f~~Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, submit a license amendment request to the Authority and receive approval by amendment. The amendment request must include a written commitment that the licensee must~~will~~, before conducting research;
(a) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and
(b) Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.
(4) Nothing in this rule relieves licensees from complying with other requirements in this chapter.[SBA3]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

General Technical Requirements

333-116-0190
Authorization for Calibration and Reference Source

Any person authorized by OAR 333-116-0030 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:
(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to OAR 333-102-0290 or equivalent provisions of the U.S. Nuclear Regulatory Commission (NRC,) Agreement State or Licensing State and that do not exceed 1.11GBq (30 mCi) each;
(2) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life of 100 days or less in individual amounts not to exceed 1.11GBq (30 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi);
(3) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 ~~u~~mCi) each; and
(4) Technetium-99m in individual amounts to exceed 1.85 GBq (50 mCi).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Imaging and Localization

333-116-0680
Training for Therapeutic Use of Radiopharmaceuticals
Except as provided in OAR 333-116-0740, the licensee must require an authorized user of unsealed byproduct material for the uses authorized under OAR 333-116-0360 to be a physician who:
(1) Is certified by a medical specialty board whose certification process has been recognized by the ~~Commission~~ NRC or an Agreement State and who meets the requirements in paragraph (2)(b)(F) and ~~subparagraph (2)(b)(I)(ii)~~ subsection (2)(c) of this rule. (Specialty boards whose certification processes have been recognized by the ~~Nuclear Regulatory Commission~~ NRC or an Agreement State shall~~will~~ be posted on the ~~Nuclear Regulatory Commission's~~ NRC's webpage). To be recognized, a specialty board shall require all candidates for certification to:
(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subsection (2)(a) through paragraph (2)(b)(E). ~~(2) and subseetion (2)(b).~~ Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and
(b) Pass an examination, administered by diplomats[SBA4] of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or
(2) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in basic radionuclide handling techniques

applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:
(a) Classroom and laboratory training in the following areas:
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(b) Work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0740, and sections (1) and (2) of this rule, or ~~Nuclear Regulatory Commission~~ NRC or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage category or categories as given in OAR 333-116-0680(2)(b)(F) as the individual requesting authorized user status. The work experience must involve:
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey instruments;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(F) Administering dosages of radiopharmaceutical drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
(i) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;
(ii) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;
NOTE: Experience with at least three cases in Category [SBA5]~~[OO6]vii)(2)~~ (ii) also satisfies the requirement in Category[SBA7] ~~(vii)(A).~~(i).
(iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; or
(iv) Parenteral administration of any other radionuclide; and
(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in sections (1) and (2) and paragraph (2)(b)(F) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0680 or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements. The preceptor authorized user, who meets the requirements in section (2) of this rule, must have experience in administering dosages in the same dosage

category or categories as given in OAR 333-116-0680(2)(b)(F)(i), (ii), (iii), or (iv) as the individual requesting authorized user status.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0683
Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)
Except as provided in OAR 333-116-0740, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive and the total treatment quantity is less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:
(1) Is certified by a medical specialty board whose certification process includes all of the requirements in section (3) of this rule and whose certification has been recognized by the ~~Nuclear Regulatory Commission~~NRC or an Agreement State and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the ~~Nuclear Regulatory Commission~~NRC or an Agreement State are posted on the ~~Nuclear Regulatory Commission~~NRC's webpage); or
(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(F)(i) or (ii) or 333-116-0687, or equivalent Agreement State requirements; or
(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.
(a) The training must include:
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0740 or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements. A supervising authorized user who meets the requirements in OAR 333-116-0680(2) must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or (ii). The work experience must involve:
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and
(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0680, 333-116-0683, 333-116-0687 or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements. A preceptor authorized user, who meets the requirement in OAR 333-116-0680(2), must also have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(i) or ~~and~~ (ii).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0687
~~Qualifications for Authorized User for Oral Administration When a Written Directive is Required~~
Training for Ooral Aadministration of Ssodium Iiodide I-131 Rrequiring a Wwritten Ddirective in Qquantities Ggreater than 1.22 Ggigabecquerels (33 millicuries).
Except as provided in OAR 333-116-0740, the licensee must require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:
(1) Is certified by a medical specialty board whose certification process includes all of the requirements in subsection (3)(a) and (3)(b) of this rule and whose certification has been recognized by the NRC~~Commission~~ or an Agreement State, and who meets the requirements in subsection (3)(c) of this rule. (The names of board certifications which have been recognized by the ~~Nuclear Regulatory Commission~~NRC or an Agreement State are posted on the ~~Nuclear Regulatory Commission~~NRC's webpage); or
(2) Is an authorized user under OAR 333-116-0680 for uses listed in OAR 333-116-0680(2)(b)(F)(ii), or equivalent ~~Nuclear Regulatory commission~~NRC or Agreement State requirements; or
(3) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.
(a) The training must include:
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(b) Has work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements. A supervising authorized user, who meets the requirements in OAR 333-116-0680(2), must have

experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(ii). The work experience must involve:
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(F) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and
(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (3)(a) and (3)(b) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under OAR 333-116-0360. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0680, 333-116-0687, 333-116-0740, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in 333-116-0680(2), must have experience in administering dosages as specified in OAR 333-116-0680(2)(b)(F)(ii).
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

333-116-0690
Training for Therapeutic Use of Brachytherapy Source
Except as provided in OAR 333-116-0740, the licensee must require the authorized user using manual brachytherapy sources specified in OAR 333-116-0420 for therapy to be a physician who:
(1) Is certified by a medical specialty board whose certification process ~~includes all of the requirements in section (2)~~ has been recognized by the NRC or an Agreement State, and who meets the requirements in subsection (2)(d) of this rule. (The names of board certifications which have been recognized by the ~~Commission~~ NRC or an Agreement State are posted on the NRC's webpage.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
(a) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
(b) Pass an examination, administered by diplomates[SBA8] of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(2) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
(a) 200 hours of classroom and laboratory training in the following areas:
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and
(b) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this rule, OAR 333-116-0740 or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements at a medical institution, involving:
(A) Ordering, receiving~~,~~ and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Checking survey meters for proper operation;
(C) Preparing, implanting~~,~~ and removing brachytherapy sources;
(D) Maintaining running inventories of material on hand;
(E) Using administrative controls to prevent a medical event involving the use of byproduct material; and
(F) Using emergency procedures to control byproduct material; and
(c) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education, or the Royal College of Physicians and Surgeons of Canada, or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by ~~paragraph~~ subsection (2)(b) of this rule; and
(d) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in OAR 333-116-0740, 333-116-0690, or equivalent ~~Nuclear Regulatory Commission~~NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (1)(a), or subsections (2)(a), (2)(b) and (2)(c) of this rule and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under OAR 333-116-0420.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 118

TRANSPORTATION OF RADIOACTIVE MATERIAL

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) ""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.
(7) ""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 containing fissile material during transportation. Determination of criticality safety index is described in 10 CFR 71.22, 71.23, and 71.59.
(8) ""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.
(9) "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.
(10) "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.
(11) "Fissile material package" means a fissile material packaging together with its fissile material contents.
(12) "~~"~~Graphite~~"~~" means for the purposes of 10 CFR 71.15 and 71.22 and graphite with a boron equivalent content less than five parts per million and density greater than 1.5 grams per cubic centimeter.
(13) "Indian tribe" means an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.
(14~~3~~) "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.
(15~~4~~) "Low specific activity (LSA) material" means radioactive material with limited specific activity that is nonfissile or is excepted[01][ANN2]-under 10 CFR 71.15, 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) Ores containing only naturally occurring radionuclides (~~e.g.,~~ [ANN3]uranium, thorium) that are not intended to be processed for the use of these radionuclides;
(B) Solid unirradiated natural uranium, depleted uranium, natural thorium, or their solid or liquid compounds or mixtures;
(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) 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 (~~e.g.,~~ [ANN4]consolidated wastes, activated materials) 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, ceramic, ~~etc.~~ [ANN5]);
(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, ~~would not~~shall not exceed 1E-1 A2; and
(C) The estimated average specific activity of the solid does not exceed 2E-3 A2 per gram.
(16~~5~~) "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.
(17~~6~~) "~~"~~Natural thorium"~~"~~ means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).
(18~~7~~) "Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "~~"~~special form radioactive material."~~".~~
(19~~8~~) "~~"~~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 ~~would~~ 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~~will~~ 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.
(20~~19~~) "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.
(21~~0~~) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.
(22~~1~~) "Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71.

(2~~3~~2) "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 and 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, 1983), and constructed before April 1, 1998, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.
(2~~4~~3) "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.
(2~~5~~4) "~~"~~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.
(2~~6~~5) "Surface contaminated object (SCO)" (~~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 microcuric/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.

(2~~7~~6) "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)).

(28) "Tribal official" means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

(2~~9~~7) "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.

(3~~0~~28) "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.

(3~~1~~29) "Type B package" means a Type B packaging together with its radioactive contents.

NOTE: A Ttype 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.

(3~~2~~0) "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.

(3~~3~~1) "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.

(3~~4~~2) "~~"~~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.

(3~~5~~3) "Uranium — natural, depleted, enriched":

(a) "Natural uranium" means uranium isotopes 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.
[ED. NOTE: Appendices referenced are available from the agency.]
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

Operating Controls and Procedures

333-118-0190
Advance Notification of Transport of Nuclear Waste
(1) Nuclear waste transports shall be transported as specified in 10 CFR Part 71.97.
(~~2~~1) Each licensee shall provide advance notification to the Governor of the State of Oregon or designee of the shipment of licensed material through or across the boundary of the state before the transport or delivery to a carrier for transport of licensed material outside the confines of the licensee's plant or other place of storage.
(3) Each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in section (4) of this rule, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
~~NOTE:~~ (4) A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State, Local, and Indian Tribe Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
~~(2) Nuclear waste transports shall be transported as specified in 10 CFR Part 71.97.~~
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807

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OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

Reports

333-120-0710
Notification of Incidents

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

(a) An individual to receive:

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

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

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

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

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

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

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

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

(C) A shallow-dose equivalent to the skin or extremities exceeding 0.5~~15~~ Sv (~~15~~ ~~sieverts or~~ rems); or

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

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

(4) Reports made by licensees, or registrants, in response to the requirements of subsections (1)(a) and (b) of this rule must be made by telephone and either by telegram, electronic mail, or facsimile to the Authority.

(5) The provisions of this rule do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under OAR 333-120-0730.
Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807