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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**

333-101-0005

Application for Registration of Radiation Machines

No X-ray machine shall~~may~~ be operated ~~on or after July 1, 1996~~ unless the registration application has been submitted by the registrant to the Authority. ~~machine has a valid X-ray machine registration.~~ Each person having a radiation machine must:

(1) Apply, in writing, for registration of such machines with the Authority prior to the operation of a radiation machine. All operable radiation machines must be registered and the appropriate fee, which is listed in division 103 of these rules, must be paid. Registration fees received by the Authority shall be refundable up to 10 calendar days if the application is withdrawn. Hospitals wishing to register any radiation machine must meet the additional requirements of OAR 333-101-0200. To avoid radiation machine registration and fees, the X-ray tube must be removed or the machine must be disassembled. Application for registration 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 of the owner or person having administrative control and responsibility for use.

"Person" is defined in OAR 333-100-0005 to include "organization";

(b) Address and telephone number where the machine is located and used except that a central headquarters address may be given for a mobile machine used at various temporary field locations;

(c) A description of the type, model and control panel serial number of the radiation machine

(state I.D. number if issued) and its rated capacity in peak kilovolts and maximum milliamperes;

(d) A description of the use (dental, medical, industrial, veterinary, research, etc.) of the machine;

(e) Date of application and signature of registrant;

(f) The individual and the signature of the individual designated under section (3) of this rule;

(g) If the facility is mobile, the geographic areas within the state to be covered; and

(h) Name of the radiation machine supplier, installer and service agent.

(2) The registrant must notify the Authority within 30 days of any change which increases the radiation output or rating of the radiation machine or of any other change which renders the information required in section (1) of this rule no longer accurate.

(3) When required by the Authority, the registrant must designate an individual who will be responsible for radiation protection for the machine. Such individual must:

(a) Be qualified by training and experience concerning all hazards and precautions involved in operating the machine for which he or she is responsible;

(b) Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these rules;

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- (c) Give instructions concerning hazards and safety practices to individuals who may be occupationally exposed to radiation from the machine; and
- (d) Make surveys and carry out other procedures as required by these rules.
- (4) When, in the opinion of the Authority, the individual designated to be responsible for radiation safety does not have qualifications sufficient to insure safe use of the machine for which he or she is responsible, the Authority may order the registrant to designate another individual who meets the requirements of this division.
- (5) Each registrant must prohibit any person from furnishing radiation machine servicing or services as described in OAR 333-101-0020(4) to his radiation machine facility until such person provides evidence that he has been licensed with the Authority as a provider of services in accordance with 333-101-0020.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - ORS 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 3-1996, f. & cert. ef. 8-9-96; PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

Exemptions

333-102-0005

Unimportant Quantities of Source Material

- (1) Any person is exempt from this division to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution or alloy.
- (2) Any person is exempt from this division to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person must not refine or process such ore.
- (3) Any person is exempt from this division and divisions 111 and 120 to the extent that such person receives, possesses, uses or transfers:
 - (a) Any quantities of thorium contained in:
 - (A) Incandescent gas mantles;
 - (B) Vacuum tubes;
 - (C) Welding rods;
 - (D) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
 - (E) Germicidal lamps, sun lamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
 - (F) Rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these; or
 - (G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(b) Source material contained in the following products:

(A) Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material;

(B) Piezoelectric ceramic containing not more than two percent by weight source material;

(C) Glassware containing more than two percent by weight source material or, for glassware manufactured before August 27, 2013, not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; or

(D) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(c) Photographic film, negatives and prints containing uranium or thorium;

(d) Any finished product or part fabricated of, or containing tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(e) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

(A) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

NOTE: The requirements specified in paragraphs (3)(e)(A) and (3)(e)(B) of this rule need not be met by counterweights manufactured prior to December 31, 1969 provided, that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend required by paragraph(3)(e)(B) of this rule in effect on June 30, 1969.

(B) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and

(C) This exemption must not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(f) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(A) The shipping container is conspicuously and legibly impressed with the legend "CAUTION — RADIOACTIVE SHIELDING — URANIUM"; and

(B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(g) Thorium or uranium contained in finished optical lenses and mirrors, provided that each lens does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that this exemption must not be deemed to authorize either:

(A) The shaping, grinding or polishing of such lens or mirrors or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(B) The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

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(h) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.

(4) The exemptions in section (3) of this rule do not authorize the manufacture of any of the products described.

(5) No person may initially transfer for sale or distribution a product containing source material to persons exempt under this rule, U.S. Nuclear Regulatory Commission or equivalent regulations of an Agreement State, unless authorized by a license issued under OAR 333-102-0300 and 333-102-0305 to initially transfer such products for sale or distribution.

(a) Persons initially distributing source material in products covered by the exemptions in this rule before August 27, 2013, without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Authority takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(b) Persons authorized to manufacture, process, or produce these materials or products containing source material by an Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under OAR 333-102-0300 and 333-102-0305 for distribution only and are exempt from the requirements of divisions 111 and 120 of this chapter, and OAR 333-102-0200(2) and (3).

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 10-1987, f. & ef. 7-28-87; HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

General Licenses

333-102-0102

Requirements for License to Initially Transfer Source Material for Use Under the Small Quantities of Source Materials General License

An application for a specific license to initially transfer source material for use under OAR 333-102-0101, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be approved if:

(1) The applicant satisfies the general requirements specified in OAR 333-102-0200; and

(2) The applicant submits adequate information on, and the Authority~~Commission~~ approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-102-0104

Conditions of Licenses to Initially Transfer Source Material for Use Under the 'Small Quantities of Source Material' General License: Quality Control, Labeling, Safety Instructions, and Records and Reports

- (1) Each person licensed under OAR 333-102-0102 shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material".
- (2) Each person licensed under OAR 333-102-0102 shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
- (3) Each person licensed under OAR 333-102-0102 shall provide the information specified in this rule to each person to whom source material is transferred for use under OAR 333-102-0101, equivalent provisions in Agreement State or the U.S. Nuclear Regulatory Commission's regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
 - (a) A copy of OAR 333-102-0101 and OAR 333-102-0330, or relevant equivalent regulations of the Agreement State or the U.S. Nuclear Regulatory Commission; and
 - (b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.
- (4) Each person licensed under OAR 333-102-0102 shall report transfers as follows:
 - (a) File a report with the Authority. The report shall include the following information:
 - (A) The name, address, and license number of the person who transferred the source material;
 - (B) For each general licensee under OAR 333-102-0101~~2~~:
 - (i) Equivalent Agreement State provisions or the Nuclear Regulatory Commission regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter;
 - (ii) The name and address of the general licensee to whom source material is distributed;
 - (iii) A responsible agent, by name and position, and phone number, of the general licensee to whom the material was sent; and
 - (iv) The type, physical form, and quantity of source material transferred.
 - (C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.
 - (b) File a report with each responsible Agreement State or U.S. Nuclear Regulatory Commission agency that identifies all persons, operating under provisions equivalent to OAR 333-102-0101~~2~~, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the Agreement State being reported to:
 - (A) The name, address, and license number of the person who transferred the source material; and
 - (B) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position and phone number of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.
 - (C) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction.
 - (c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under OAR 333-102-0101 or equivalent Agreement State or U.S. Nuclear Regulatory Commission's provisions during the

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current period, a report shall be submitted to the Authority indicating so. If no transfers have been made to general licensees in a particular Agreement State or U.S. Nuclear Regulatory Commission's jurisdiction during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency

(5) Each person licensed under OAR 333-102-0102 shall maintain all information that supports the reports required by this rule concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Authority, Agreement State agency, or the U.S. Nuclear Regulatory Commission.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

General Licenses — Radioactive Material Other than Source Material

333-102-0190

Application for Specific Licenses

(1) Applications for specific licenses must be filed on a form prescribed by the Authority. Information contained in previous applications, statements or reports filed with the Authority, the US Nuclear Regulatory Commission, or an Agreement State or a Licensing State or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(2) The Authority may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Authority to determine whether the application shall be granted or denied or whether a license shall be modified or revoked.

(3) Each application must be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

(4) Each applicant for a specific license is required to have a permanent in-state office with a copy of all required records available for inspection by the Authority.

(5) An application for a license filed pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with rules of the Authority and the US Nuclear Regulatory Commission as to applications for such licenses.

(6) Each new application for a radioactive material license must be accompanied by the fee prescribed by OAR 333-103-0010. Fees received by the Authority shall be refundable up to 10 calendar days if the application is withdrawn. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in OAR 333-103-0010.

(7) An application for a license to receive and possess radioactive material for the conduct of any activity that the Authority has determined, pursuant to Subpart A of Part 51 of 10 CFR (Environmental Protection Regulations applicable to materials licensing), will significantly affect the quality of the environment, must be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and must be accompanied by any Environmental Report required pursuant to Subpart A of 10 CFR Part 51.

(8) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(a) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR Part 32.210 or with an Agreement State; or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR Parts 32.210; or

(b) Contain the information identified in 10 CFR Part 32.210(c); or

(c) For sources or devices manufactured prior to October 23, 2012 that are not registered with the Nuclear Regulatory Commission or an Agreement State which the applicant is unable to provide all categories of information specified in 10 CFR Part 32.210(c) the applicant must provide:

(A) All available information identified in 10 CFR Part 32.210(c) concerning the source and if applicable the device; and

(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Information must include a description of the source or device, description of radiation safety features, intended use and associated operating experience and the results of a recent leak test:

(i) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR Part 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity; or

(ii) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(9) As provided by OAR 333-102-0200, certain applications for specific licenses filed under this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning as follows:

(10)(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in 10 CFR 30.72, "Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(A) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials shall not exceed one rem effective dose equivalent or five rems to the thyroid; or

(B) An emergency plan for responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under paragraph (10)(a)(A) of this rule:

(A) The radioactive material is physically separated so that only a portion could be involved in an accident;

(B) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(C) The release fraction in the respirable size range shall be lower than the release fraction shown in 10 CFR Part 30.72 (Schedule C — Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release) due to the chemical or physical form of the material;

(D) The solubility of the radioactive material shall reduce the dose received;

(E) Facility design or engineered safety features in the facility shall cause the release fraction to be lower than shown in 10 CFR Part 30.72;

(F) Operating restrictions or procedures shall prevent a release fraction as large as that shown in 10 CFR Part 30.72; or

(G) Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under paragraph (10)(a)(B) of this rule must include the following information:

(A) Facility description. A brief description of the licensee's facility and area near the site.

(B) Types of accidents. An identification of each type of radio-active materials accident for which protective actions may be needed.

(C) Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

(D) Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

(E) Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(F) Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

(G) Responsibilities. A brief description of the responsibilities of licensee personnel if an accident occurs, including identification of personnel responsible for promptly notifying offsite response organizations and the Authority; also responsibilities for developing, maintaining, and updating the plan.

(H) Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee also must commit to notify the Authority immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

NOTE: These reporting requirements do not ~~superecede~~supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

(I) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Authority.

(J) Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee can offer to fire, police, medical and other emergency personnel. The training must familiarize personnel with site-specific emergency procedures. Also, the training must thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(K) Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

(L) Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee must invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios must not be known to most exercise participants. The licensee must critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(M) Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(N) An application from a medical facility, educational institution, or federal facility to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 10 CFR Part 35 or division 116 of this chapter or equivalent Agreement State requirements shall include:

(i) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(ii) Evidence that the applicant is qualified to produce radiopharmaceutical drugs for medical use by meeting one of the criteria in 10 CFR 32.72(a)(2).

(iii) Identification of individual(s) authorized to prepare the PET radiopharmaceutical drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in OAR 333-116-0880 and 333-116-0910.

(iv) Information identified in 10 CFR Part 32.72(a)(3) on the PET radiopharmaceutical to be non-commercially transferred to members of its consortium.

(v) Each applicant for a license for byproduct material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in 10 CFR Parts 73.21, 73.22 and 73.23 as applicable.

(d) The licensee must allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Authority. The licensee must provide any comments received within the 60 days to the Authority with the emergency plan.

[Publications: Publications referenced are available from the agency.]

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

DIVISION 103

FEES

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(F);
- (b) Basic License, \$1,220(F);
- (c) Brachytherapy, \$2,755(F);
- (d) Broad Scope A, \$3,000(F);
- (e) Broad Scope B, \$2,755(F);
- (f) Broad Scope C, \$1,370(F);
- (g) Distribution, \$1,370(F);
- (h) Fixed Gauge, \$345(S);
- (i) High, medium and low dose rate brachytherapy, \$3,000(S);
- (j) Imaging and Localization, \$1,370(F);
- (k) In Vitro Laboratory, \$455(F);
- (l) Industrial Radiography:
 - (A) Fixed Facility, \$3,000(F);
 - (B) Field Use, \$3,000(F);
- (m) Instrument Calibration, \$1,035(S);
- (n) Investigational New Drug, \$2,065(F);
- (o) Irradiator Self-Shielded, \$1,370(S);
- (p) Manufacturing/Compounding, \$3,000(F);
- (q) Mobile Nuclear Medicine, \$3,000(F);
- (r) NORM (no processing), \$920(F);
- (s) Nuclear Pharmacy, \$3,000(F);
- (t) Other Measuring Device, \$200(S). Six sources or more, for attenuation purposes, may apply for a basic license;
- (u) Portable Gauge:
 - (A) X-ray Fluorescence, \$690(S);
 - (B) All other portable gauges, \$920(S);
- (v) Radiopharmaceutical Therapy, \$2,065(F);
- (w) RAM/NOS Facility, \$3,000(F);
- (x) Research & Development, \$2,065(F);
- (y) Sealed Sources for Diagnosis, \$690(S);
- (z) Source Material, \$3,000(F);
- (aa) Special Nuclear Material (sealed), \$1,370(S);
- (bb) Special Nuclear Material (unsealed), \$3,000(F);
- (cc) Teletherapy (external beam), \$3,000(S);
- (dd) Unique, No Fee;
- (ee) Uptake and Dilution, \$920(F);

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- (ff) Use of Xenon Gas, \$920(F);
- (gg) Waste Packaging, \$3,000(F);
- (hh) Well Logging, \$2,065(S);

NOTE: (F) means facility; (S) means source.

(3) Each specific license validation fee shall be due and payable:

(a) Based 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.

(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, pursuant to subsection (2)(b) of this rule.

Stat. Auth.: ORS 453.757

Stats. Implemented: ORS 453.757

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 13-1988, f. 6-7-88, cert. ef. 7-1-88; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1991, f. & cert. ef. 10-1-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 2-1995(Temp), f. & cert. ef. 7-11-95; HD 4-1995, f. & cert. ef. 9-8-95; HD 3-1996, f. & cert. ef. 8-9-96; PH 11-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 24-2014, f. & cert. ef. 8-15-14

DIVISION 106

X-RAYS IN THE HEALING ARTS

333-106-0005

Definitions

As used in this division, the following definitions apply:

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

- (1) "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.
- (2) "Added Filtration" means any filtration that is in addition to the inherent filtration.
- (3) "Aluminum Equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.
NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
- (4) "Applications Training" means a vendor or manufacturer providing training for specific X-ray equipment.
- (5) "A.R.R.T." means the American Registry of Radiologic Technologists.
- (6) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.
- (7) "Attenuation Block" means a block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
- (8) "Authority approved instructor" means an individual who has been evaluated and approved by the Authority to teach Radiation Safety.
- (9) "Authority approved training course" means a course of training that has been evaluated and approved by the Authority.
- (10) "Automatic Exposure Control (AEC)" means a device that automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Photo timer".)
- (11) "Barrier" (see "Protective Barrier").
- (12) "Beam Axis" means a line from the source through the centers of the X-ray fields.
- (13) "Beam-Limiting Device" means a device that provides a means to restrict the dimensions of the X-ray field.
- (14) "Beam Monitoring System" means a system designed to detect and measure the radiation present in the useful beam.
- (15) "C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.
- (16) "Cephalometric Device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (17) "Certified Components" means components of X-ray systems that are subject to the X-ray Equipment Performance Standards promulgated under Public Law 90-602, the Radiation Control Agency for Health and Safety Act of 1968.
- (18) "Certified System" means any X-ray system that has one or more certified component(s).
- (19) "Changeable Filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
- (20) "Coefficient of Variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.
- (21) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

- (22) "Computed radiography (CR)" means creating an X-ray image using plates consisting of a photo stimulable phosphor (PSP) that when exposed to radiation and then processed by a scanner, provides the information to a computer for display and manipulation.
- (23) "Contact Therapy System" means an X-ray system used for therapy with the tube port placed in contact with or within five centimeters of the surface being treated.
- (24) "Control Panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
- (25) "Cooling Curve" means the graphical relationship between heat units stored and cooling time.
- (26) "Dead-Man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (27) "Detector" (see "Radiation detector").
- (28) "Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission, and reception of X-rays and the transformation, storage, and visual display of the resultant X-ray image.
- (29) "Diagnostic Source Assembly" means the tube housing assembly with a beam-limiting device attached.
- (30) "Diagnostic-Type Protective Tube Housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 milliroentgens (mR) in one hour when the tube is operated at its leakage technique factors.
- (31) "Diagnostic X-ray System" means an X-ray system designed for irradiation of any part of the human body or animal body for the purpose of diagnosis or visualization.
- (32) "Direct Digital Radiography (DR)" means creating an X-ray image by sending signals directly from a digital image receptor to a computer for display and manipulation.
- (33) "Direct Scattered Radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").
- (34) "Entrance Exposure Rate" means the exposure free in air per unit of time.
- (35) "Field Emission Equipment" means equipment which uses a tube in which electron emission from the cathode is due solely to the action of an electric field.
- (36) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
- (37) "Fluoroscopic Benchmark" means a standard based upon the average cumulative fluoroscopic on-time normally found to be used for a specific fluoroscopic procedure at the site.
- (38) "Fluoroscopic Imaging Assembly" means a subsystem in which X-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
- (39) "Fluoroscopic X-ray equipment operator" means any individual who, adjusts technique factors, activates the exposure switch or button of a fluoroscopic X-ray machine or physically positions patients or animals. Human holders, used solely for immobilization purposes (example being veterinarian human holders) are excluded from this rule.
- (40) "Focal Spot" means the area projected on the anode of the tube by the electrons accelerated from the cathode and from which the useful beam originates.
- (41) "General Purpose Radiographic X-ray System" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- (42) "Gonad Shield" means a protective barrier for the testes or ovaries.

- (43) "Half-Value Layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (44) "Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an Oregon licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.
- (45) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, example being kVp x mA x second.
- (46) "HVL" (see "Half-value layer").
- (47) "Image Intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.
- (48) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.
- (49) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
- (50) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
- (51) "Irradiation" means the exposure of matter to ionizing radiation.
- (52) "Kilovolt-Peak" (see "Peak tube potential").
- (53) "kV" means kilovolts.
- (54) "kVp" (see "Peak tube potential").
- (55) "kWs" means kilowatt second.
- (56) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (57) "Leakage Radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:
- (a) The useful beam; and
 - (b) Radiation produced when the exposure switch or timer is not activated.
- (58) "Leakage Technique Factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:
- (a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, example being 10 milliamperere seconds (mAs), or the minimum obtainable from the unit, whichever is larger.
 - (b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.
 - (c) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

- (59) "Light Field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- (60) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.
- (61) "mA" means milliampere.
- (62) "mAs" means milliamperere second.
- (63) "Maximum Line Current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.
- (64) "Mobile Equipment" (see "X-ray Equipment").
- (65) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and
- (a) Are not specifically certified in diagnostic or therapeutic use of X-rays; and
- (b) Are currently licensed by their respective Oregon licensing board.
- (66) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended.
- (67) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.
- (68) "Peak Tube Potential" means the maximum value of the potential difference across the X-ray tube during an exposure.
- (69) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.
- (70) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
- (71) "PID" (see "Position indicating device").
- (72) "Portable Equipment" (see "X-ray Equipment").
- (73) "Position Indicating Device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
- (74) "Primary Dose Monitoring System" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.
- (75) "Primary Protective Barrier" (see "Protective barrier").
- (76) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
- (77) "Protected Area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:
- (a) 2 milliroentgens (mR) in any one hour; or
- (b) 100 mR in any one year.
- (c) See OAR 333-120-0180 for additional information.

(78) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;

(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(79) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

(80) "Qualified Expert" means an individual, approved by the Authority, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:

(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the general supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or

(c) Receive approval from the Authority for specific activities.

(81) "Quality Control Program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The X-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.

(82) "Radiation Detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(83) "Radiation Therapy Simulation System" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(84) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.

(85) "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

(86) "Radiological Physicist" means an individual who:

(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or

(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

(c) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics;

and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

(87) "Radiologist" or "Oral Radiologist" means a physician or dentist trained in the diagnostic ~~or therapeutic~~ use of X-rays and who is;

(a) Currently licensed by their respective Oregon licensing board; and

(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon; or

(c) Have become eligible for the ABR exam within six years of successfully completing the Accreditation Council for Graduate Medical Education accredited diagnostic radiology residency program.

(88) "Radiology Physician's Assistant" (R.P.A.)/ "Registered Radiology Assistant" (R.R.A.).

(a) An R.P.A. means an American Registry of Radiologic Technologists (A.R.R.T.) technologist who has successfully completed an advanced training program and is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA).

(b) An R.R.A means an A.R.R.T. technologist who has successfully completed an advanced training program and is certified by A.R.R.T.

(89) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Medical Imaging.

(90) "Rating" means the operating limits as specified by the component manufacturer.

(91) "Recording" means producing a permanent form of an image resulting from X-ray photons.

(92) "Registrant," as used in this division, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans, animals or materials to the useful beam of the system and is required by the provisions contained in divisions 100 and 101 of this chapter to register with the Authority.

(93) "Response Time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.

(94) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").

(95) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.

(96) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.

(97) "Secondary Protective Barrier" (see "Protective barrier").

(98) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

(99) "SID" (see "Source-image receptor distance").

(100) "Source" means the focal spot of the X-ray tube.

(101) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.

- (102) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.
- (103) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- (104) "Spot-Film Device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- (105) "SSD" means the distance between the source and the skin of the patient.
- (106) "Stationary Equipment" (see "X-ray Equipment").
- (107) "Stray Radiation" means the sum of leakage and scattered radiation.
- (108) "Supervision" means the supervising individual routinely reviews and monitors the work being performed. There are three categories of supervision:
- (a) "General Supervision" means that the supervisor is not required to be on-site, but must be available for direct communication, either in person, by telephone, or other electronic means.
 - (b) "Direct Supervision" means that the supervisor is physically present in the building and immediately available to furnish assistance as needed.
 - (c) "Personal Supervision" means that the supervisor is physically present in the room during the performance of the procedure at all times.
- (109) "Technique Factors" means the conditions of operation. They are specified as follows:
- (a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
 - (b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of X-ray pulses;
 - (c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
- (110) "Termination of Irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- (111) "Traceable to a National Standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- (112) "Tube" means an X-ray tube, unless otherwise specified.
- (113) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when such are contained within the tube housing.
- (114) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- (115) "Unprotected Area" means any area in which the exposure rate, due to the use of the radiation machine under normal operating procedures and workload, exceeds any of the following limits:
- (a) Two mR in any one hour;
 - (b) 100 mR in any seven consecutive days; or
 - (c) 500 mR in any one year.

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(116) "Useful Beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

(117) "Variable-Aperture Beam-Limiting Device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

(118) "Visible Area" means that portion of the input surface of the image receptor over which the incident X-ray photons are producing a visible image.

(119) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

(120) "X-ray Control" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as exposure switches (control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

(121) "X-ray Equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:

(a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and casters for moving while completely assembled and intended to be taken from one geographical location to another or from one room to another;

(b) "Portable equipment" means X-ray equipment designed to be hand-carried but not hand-held during operations.

(c) "Stationary equipment" means X-ray equipment which is installed in a fixed location; such as bolted to the floor or wall;

(d) "Transportable" means X-ray equipment installed in a vehicle or trailer;

(e) "Hand-held unit" means a ~~self-contained~~self-contained X-ray machine designed so that it can be held in one or two hands to perform intra-oral radiography or other Authority approved radiography.

(122) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of an X-ray machine, or physically positions patients or animals for a radiograph (see "Operator").

(123) "X-ray Field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(124) "X-ray High-Voltage Generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

(125) "X-ray System" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(126) "X-ray Subsystem" means any combination of two or more components of an X-ray system for which there are requirements specified in this division.

(127) "X-ray Tube" means any electron tube which is designed to be used primarily for the production of X-rays.

[ED. NOTE: Equations referenced are available from the agency.]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 20-2010, f. & cert. ef. 9-1-10; PH 5-2011(Temp), f. & cert. ef. 7-1-11 thru 12-27-11; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

General Requirements

333-106-0035

Deliberate Exposures Restricted

Persons shall not be exposed to the useful beam except for healing art purposes until the patient has been evaluated, and a medical need for the X-ray/s is determined, and has been authorized by a physician or Dental Professional licensed to practice the healing arts, ~~in Oregon~~. Any useful diagnostic information obtained from each exposure shall be reviewed by a practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

- (1) Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.
- (2) Exposure of an individual for the purpose of healing arts screening:
 - (a) Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Authority;
 - (b) When requesting such approval, that person shall submit the following information:
 - (A) Name and address of the applicant and, where applicable, the names and addresses of agents within this state;
 - (B) Diseases or conditions for which the X-ray examinations are to be used in diagnoses;
 - (C) A detailed description of the X-ray examinations proposed in the screening program to include the estimated total radiation dose received by the individual(s) participating in the screening program;
 - (D) Description of the population to be examined in the screening program, i.e., age, sex, physical conditions, and other appropriate information;
 - (E) An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;
 - (F) An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these rules;
 - (G) A description of the diagnostic film quality control program;
 - (H) A copy of the technique chart for the X-ray examination procedures to be used;
 - (I) The qualifications of each individual who will be operating the X-ray system(s);
 - (J) The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;
 - (K) The name and address of the individual who will interpret the radiograph(s);

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(L) A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

(M) A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

(3) If any information submitted to the Authority under subsection (2)(b) changes, the Authority shall be immediately notified.

(4) Mammography screening shall be exempt from the requirements of section (2) of this rule if the following conditions are met:

(a) The requirements set forth in OAR 333-106-0700 to 333-106-0750 of these rules are satisfied.

(b) All other applicable rules are met.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

Fluoroscopic X-ray Systems Requirements

333-106-0205

Activation of the Fluoroscopic Tube

(1) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(2) Proper training in the operation of fluoroscopic X-ray equipment is required for all operators and shall include but not be limited to the following:

(a) Principles and operation of the fluoroscopic X-ray machine:

(A) Generating X-rays;

(B) kVp and mA;

(C) Image intensification;

(D) High level control versus standard operating mode;

(E) Magnification (multi-field);

(F) Automatic Brightness Control (ABC);

(G) Pulsed versus continuous X-ray dose rates;

(H) Image recording modes;

(I) Imaging Systems (TV and Digital); and

(J) Contrast, noise and resolution.

(b) Radiation units:

(A) Traditional units;

(B) SI units; and

(C) Dose Area Product.

(c) Typical fluoroscopic outputs:

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- (A) Patient skin entrance dose;
 - (B) Standard Roentgen per minute (R/min) dose rates; and
 - (C) High level/Boost enable Roentgen per minute (R/min) dose rates.
 - (d) Dose reduction techniques for fluoroscopy:
 - (A) Collimation;
 - (B) X-ray tube and image intensifier placement;
 - (C) Patient size versus technique selection;
 - (D) Grid use;
 - (E) Last image hold;
 - (F) Additional beam filtration;
 - (G) Gantry angles;
 - (H) Use of spacer cone; and
 - (I) Pulsed fluoroscopy.
 - (e) Factors affecting personnel dose:
 - (A) Patient dose;
 - (B) Scatter radiation;
 - (C) Tube and image intensifier placement; and
 - (D) Time, distance and shielding.
 - (f) Protective devices:
 - (A) Lead aprons and gloves;
 - (B) Thyroid collars;
 - (C) Protective glasses;
 - (D) Leaded drapes;
 - (E) Bucky slot cover; and
 - (F) Protective shields/barriers.
 - (g) Radiation exposure monitoring:
 - (A) Personnel monitors;
 - (B) Placement of personnel monitors; and
 - (C) Occupational and non-occupational dose limits.
 - (h) Biological effects of X-ray radiation:
 - (A) X-rays and particulate matter;
 - (B) Absorption variables (field size, dose rate, as an example);
 - (C) Scatter radiation;
 - (D) Cell sensitivity;
 - (E) Acute effects; and
 - (F) Latent effects.
 - (i) Applicable regulations:
 - (A) Federal; and
 - (B) Oregon Administrative Rules for the Control of Radiation to include, but not limited to, chapter 333, divisions 101, 103, 106, 111 and 120.
- (3) The operation of fluoroscopic equipment shall be performed by a properly trained operator. The following categories of operators are considered to have met the training requirements in section (2) of this rule:
- (a) Radiologists currently licensed in Oregon;

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(b) Non-Radiologist practitioners who have successfully completed a training program from an Authority approved resource or have been operating fluoroscopic equipment prior to April 11, 2005;

(c) Radiologic Technologists who have a permanent or temporary license from the Oregon Board of Medical Imaging (OBMI) to practice radiography;

(d) Physician assistants who have a fluoroscopy permit from the Oregon Board of Medical Imaging;

~~(e)~~ R.P.A.s and R.R.A.s who are licensed by the OBMI; and

~~(f)~~ Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405.

(4) Supervision requirements for operators of fluoroscopic equipment. The operation of fluoroscopic equipment by properly trained operators must comply with the following supervisory requirements:

(a) Radiologists may operate fluoroscopic equipment with no supervision.

(b) Non-radiologist practitioners who have had proper training in the use and operation of fluoroscopic X-ray equipment may operate fluoroscopic equipment without supervision provided that the registrant arranges to have a radiologist or medical or health physicist assist in:

(A) Developing fluoroscopic and radiation safety policies and procedures;

(B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and

(C) At least annually, review the registrant's fluoroscopy program. The review includes an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.

(c) Radiologic Technologists who have a permanent or temporary license from the OBMI to practice radiography may operate fluoroscopic equipment under the personal or direct supervision of a radiologist or a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment.

(d) Physician assistants with fluoroscopy permits may operate fluoroscopic equipment if:

(A) The supervising physician with whom the physician assistant has entered into a practice agreement is in the room where the fluoroscopic procedure is taking place at the time that the procedure is taking place; or

(B) The supervising physician with whom the physician assistant has entered into a practice agreement is in the building where the fluoroscopic procedure is taking place, and a radiographer with a license from the Oregon Board of Medical Imaging is in the room where the procedure is taking place, at the time that the procedure is taking place.

~~(e)~~ R.R.A.s or R.P.A.s may operate fluoroscopic equipment under the direct supervision of a radiologist.

(f) Physician assistants licensed with the Oregon Medical Board while completing specific clinical experience pre-requisites to become eligible to take the OBMI fluoroscopy permit examination, may operate fluoroscopy equipment under personal supervision of the physician assistant's supervising physician, licensed radiologist, licensed radiographer or medical physicist.

~~(g)~~ Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405, may operate fluoroscopic equipment under the personal supervision of a radiologist or an R.T. while in the clinical phase of training.

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- (5) The operation of fluoroscopic equipment is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.
- (6) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.
- (7) All images formed by the use of fluoroscopy shall be viewed, directly or indirectly, and interpreted by a radiologist, cardiologist, non-radiologist practitioner or other qualified specialist. R.R.A.s and R.P.A.s may issue a preliminary report; however, the final report must be issued by their supervising radiologist.
- (8) Written procedures for fluoroscopic X-ray equipment operators shall be available at the worksite and include:
- (a) A list of all individuals who are permitted to operate fluoroscopic X-ray equipment at the facility;
 - (b) A list of the fluoroscopic X-ray equipment that each operator is qualified to operate;
 - (c) Written procedures regarding the set up and operation of each fluoroscopic X-ray machine registered to the facility;
 - (d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and
 - (e) The name and title of the individual who is responsible for overseeing the fluoroscopy program.
- (9) Facilities shall determine, or cause to be determined, the typical patient entrance exposure rate for their most common fluoroscopic examinations. The determination shall be made using an attenuation block as described in OAR 333-106-0005(7) using measurement protocol in compliance with OAR 333-106-0210 and expressed in Roentgens per minute (R/min.) or milliRoentgens per minute (mR/min.). In addition, these entrance exposure rates shall be posted in the room where fluoroscopic examinations are conducted so that they are readily available to administrators, X-ray operators, patients and practitioners.
- (10) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patient's name, the type of examination, the date of the examination, the fluoroscopist's name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on-time for each fluoroscopic examination and:
- (a) Established cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at the facility's site in each of the following categories:
 - (A) Routine procedures performed on adults;
 - (B) Routine procedures performed on children;
 - (C) Orthopedic procedures performed in surgery;
 - (D) Urologic procedures performed in surgery;
 - (E) Angiographic procedures performed; and
 - (F) Interventional cardiac studies.
 - (b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;
 - (c) Take appropriate action when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have

exceeded the benchmarks established by the facility for a particular procedure more than 10 percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective actions taken, must be available for Authority review. Corrective actions, at a minimum, include:

(A) Notification of the individual; and

(B) Recommendation that the individual undergo additional coaching and training in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 4-1985, f. & ef. 3-20-85; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15

Additional Requirements for Radiographic Machines

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.

(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) 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: $(T) > 5 (T_{max} - T_{min})$.

(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(77), 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 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 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 (E_{max}) minus the minimum exposure (E_{min}): $E > 5 (E_{max} - E_{min})$

(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 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 section (2) of this rule or its updated version;

(d) Dental fluoroscopy without image intensification shall not be used; and

(e) 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 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:

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- (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.
- (e) 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)(e) of this rule may not be sold, distributed or used in the State of Oregon.
- (9) Hand-held dental X-ray administrative controls.
 - ~~(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(5).~~
 - (aA) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.
 - (bB) 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(~~98~~) before using a hand-held unit. Training on the safe use of the unit shall be documented and include at a minimum:
 - (A) Proper positioning of the unit to ensure an adequate protected position;
 - (B) Limitations on the use of position indicating devices that require longer distances to the patient's face;
 - (C) Diagrams such as drawings, illustrations, or schematics of protected position and location in relationship to the unit;
 - (D) Diagrams such as drawings, illustrations, or schematics of the effect of improper distance or removal of shielding device; and
 - (E) Diagrams such as drawings, illustrations, schematics 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

Hist.: HD 4-1985, f. & ef. 3-20-85; HD 1-1991, f. & cert. ef. 1-8-91; HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 14-2008, f. & cert. ef. 9-15-08; PH 20-2010, f. & cert. ef. 9-1-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11; PH 4-2013, f. & cert. ef. 1-29-13; PH 24-2014, f. & cert. ef. 8-15-14; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15; PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Mammography Requirements

333-106-0710

Equipment Standards

Only x-ray systems meeting the design and performance standards required under Mammography Quality Standards Act (MQSA) shall be used, unless otherwise specified in the following rules.

- (1) System design. The x-ray system shall be specifically designed for mammography.
- (2) Image receptor.
 - (a) Image receptor systems shall be specifically designed, or appropriate for mammography.
 - (b) Systems using screen-film image receptors shall provide, at a minimum, image receptor sizes of 18 X 24 and 24 X 30 cm.
 - (c) An adequate number of image receptors shall be provided to accommodate the resting period recommended by the manufacturer.
- (3) Target/filter. The x-ray system shall have the capability of providing kVp/target/filter combinations compatible with image receptor systems meeting the following requirements;
 - (a) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.
 - (b) When more than one target is provided, the system shall indicate, prior to exposure, the preselected target material.
 - (c) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after exposure, the target material and/or focal spot actually used during the exposure.
- (4) Beam quality: When used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam shall have a minimum half-value layer (HVL). The minimum HVL, for mammography equipment designed to operate below 50 kVp, is determined by dividing the actual kVp by 100, and is expressed in mm Al equivalent.
- (5) Resolution: Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining system resolution.
 - (a) Each x-ray system used for mammography, in combination with the mammography screen-film combination used, shall provide a minimum resolution of 11 Cycles/mm (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
 - (b) The bar pattern shall be placed 4.5 cm above the image receptor support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.
- (6) Compression.
 - (a) All mammography systems shall incorporate a compression device capable of compressing the breast with a force of at least 25 pounds.
 - (b) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds and 45 pounds.
 - (c) All mammography systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. The compression paddle shall:

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(A) Be flat and parallel to the image receptor support and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied. If the compression paddle is not designed to be flat and parallel to the image receptor support during compression, it shall meet the manufacturer's design specifications and maintenance requirements;

(B) Have a chest wall edge that is straight and parallel to the edge of the image receptor support;

(C) Clearly indicate the size and available positions of the detector at the x-ray input surface of the compression paddle;

(D) Not extend beyond the chest wall edge of the image receptor support by more than 1 percent of the SID when tested with the compression paddle placed above the support surface at a distance equivalent to a standard breast thickness;

(E) Shall not be visible, at its vertical edge, on the image.

(d) When equipped with a compression paddle height digital display, the display shall accurately represent the actual height of the compression paddle to within ± 0.5 cms. Testing shall be performed according to manufacturer's specifications.

(7) System capabilities. A mammographic x-ray system utilizing screen-film image receptors shall:

(a) Be equipped with moving grids matched to all image receptor sizes provided.

(b) Provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid, magnification; and various target-filter combinations.

(A) The automatic exposure control shall be capable of maintaining film optical density (OD) within $+0.30$ of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 cms and the kVp is varied appropriately for such thicknesses over the kVp range used clinically. If this requirement cannot ~~can not~~ be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different thicknesses and compositions that must be used so that optical densities within $+ 0.30$ of the average under photo- timed conditions can be produced.

(B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) to within $+ 0.15$ of the mean optical density when thicknesses of a homogeneous material are varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically.

(8) Breast entrance kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

(9) Collimation.

(a) All mammography systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. Under no circumstances, shall the x-ray field extend beyond the non-chest wall edges of the image receptor support.

(b) The total misalignment of the edges of the visually defined light field with the respective edges of the X-ray field either along the length or width of the visually defined field shall not exceed 2 percent of the SID.

(10) Kilovoltage peak (kVp) accuracy and reproducibility;

(a) The kVp, shall be accurate within $+ 5$ percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, and the most commonly used, and highest available clinical kVp; and

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(b) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(11) Dose. The average glandular dose delivered during a single cranio-caudal view of an FDA accepted phantom simulating a standard breast, shall not exceed 250 millirad (mRad) (2.5 milliGy). The dose shall be determined with technique factors and conditions used, by the registrant, clinically for a standard breast. The testing protocol used shall be the same as used by MQSA.

(a) If the average glandular dose exceeds 250 mRad (2.5 milliGray) but is no greater than 275 mRad (2.75 milliGray), patient mammography may be continued until the cause of the problem is determined and corrected. Correction must be completed within 30 working days of when the registrant became aware of the problem. If correction has not been completed within 30 working days, and the registrant has not requested an extension in writing from the Authority, patient mammography must cease until correction of the dose problem has occurred.

(b) If the average glandular dose exceeds 275 mRad (2.5 milliGray), patient mammography must cease until the cause of the dose problem is determined and corrected.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 15-1994, f. & cert. ef. 5-6-94; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 5-2005, f. & cert. ef. 4-11-05; PH 12-2006, f. & cert. ef. 6-16-06

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

333-116-0020

Definitions

As used in this division, the following definitions apply:

(1) "Address of use" means the building or buildings identified on the license as the location(s) where radioactive material may be received, used, or stored.

(2) "Area of use" means location(s) at the address of use set aside for the purpose of receiving, using or storing radioactive material.

(3) "Attestation" means required training, experience and appropriate board certification is validated using the Nuclear Regulatory Commission's form 313A.

(4) "Authorized Medical Physicist" means an individual who:

(a) Meets the requirements in OAR 333-116-0730, or 333-116-0905 and 333-116-0760; or

(b) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the Authority or an Agreement State or the US Nuclear Regulatory Commission;

(B) A medical use permit issued by a Commission master material licensee;

(C) A permit issued by a Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a Commission master material license broad scope medical use permittee.

(5) "Authorized nuclear pharmacist" means a pharmacist who:

(a) Meets the requirements in OAR 333-116-0910 and 333-116-0915;

- (b) Is identified as an authorized nuclear pharmacist on an Authority, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the use of radioactive material in the practice of nuclear pharmacy;
- (c) Is identified as an authorized nuclear pharmacist on a license issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission specific licensee of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy; or
- (d) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy licensed (authorized) by the Authority, the U.S. Nuclear Regulatory Commission, or an Agreement State to approve authorized nuclear pharmacists.
- (6) "Authorized user" means a physician, dentist or podiatrist who:
- (a) Meets the requirements listed in OAR 333-116-0660, 333-116-0670, 333-116-0680, 333-116-0683, 333-116-0687, 333-116-0690, 333-116-0700, 333-116-0710, 333-116-0720, and 333-116-0740;
- (b) Is identified as an authorized user on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or
- (c) Is identified as an authorized user on a permit issued by an Authority, Agreement State, or U.S. Nuclear Regulatory Commission licensee of broad scope that is authorized to permit the medical use of radioactive material.
- (7) "Black Box" means the radiopharmaceutical production purification system used in a PET facility.
- (8) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.
- (9) "Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose of radiation within a few centimeters, by surface, intracavitary, or interstitial application that is not designed to be disassembled by the user.
- (10) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.
- (11) "Dental use" means the intentional external administration of the radiation from radioactive material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- (12) "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.
- (13) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.
- (14) "High dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate in excess of two gray (200 rad) per hour, to the point or surface where the dose is prescribed.
- (15) "Human Research Subject" means a living person that an authorized user, conducting research, obtains data resulting from the intentional internal or external administration of

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radioactive material, or the radiation from radioactive material, to the individual. For the purpose of these rules, unless otherwise noted, the term patient applies to a human research subject.

(16) "Low dose-rate remote afterloader" means a device that remotely delivers a brachytherapy source, with a dose rate of less than two gray (200 rad) per hour, to the point or surface where the dose is prescribed.

(17) "Management" means the chief executive officer or that individual's designee.

(18) "Manual Brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed on, or in close proximity, to the treatment site or inserted directly into the tissue volume.

(19) "Medical Event ~~or Medical Error~~" means an event where a patient or human research subject:

(a) Receives a dose that differs from the prescribed dose by: ~~or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;~~

(A) The total dose delivered differs from the prescribed dose by 20 percent or more; or

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or

(D) A dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(b) A "Medical Event" shall have occurred when:

(A) An administration of a wrong radiopharmaceutical drug containing radioactive material; or

(B) An administration of a radiopharmaceutical drug containing radioactive material by the wrong route of administration; or

(C) An administration of a dose or dosage to the wrong individual or human research subject; or

(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(E) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

~~(b) Receives a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or~~

(c) An event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician shall be considered as a medical event.

(d) A leaking sealed source shall be considered as a medical event.

(20) "Medical institution" means an organization in which more than one medical discipline is practiced.

(21) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

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(22) "Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

~~(23) "Misadministration" means the administration of:~~

~~(a) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:~~

~~(A) Involving the wrong individual or wrong radiopharmaceutical; or~~

~~(B) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceed 1.11 megabecquerels (30 uCi).~~

~~(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:~~

~~(A) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or~~

~~(B) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.~~

~~(c) A gamma stereotactic radiosurgery radiation dose:~~

~~(A) Involving the wrong individual or wrong treatment site; or~~

~~(B) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.~~

~~(d) A teletherapy radiation dose:~~

~~(A) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;~~

~~(B) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;~~

~~(C) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or~~

~~(D) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.~~

~~(e) A brachytherapy radiation dose:~~

~~(A) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);~~

~~(B) Involving a sealed source that is leaking;~~

~~(C) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or~~

~~(D) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.~~

~~(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131:~~

~~(A) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; or~~

~~(B) When the dose to the individual exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.~~

(234) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(245) "Nuclear Pharmacist" means an authorized nuclear pharmacist, as defined in OAR 333-116-0020, who has received additional training, pursuant to OAR 333-116-0910 and 333-116-

0915 in the management and handling of radiopharmaceutical drugs and is authorized by license to receive, use, transfer, and dispose of such radiopharmaceutical drugs.

(~~256~~) "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(~~267~~) "Patient Intervention" means actions taken by a patient or human research subject, whether intentional or unintentional, interrupt or terminate the administration of radioactive materials or radiation.

(~~278~~) "PET" means Positron Emission Tomography.

(~~289~~) "PET Isotope Nuclear Pharmacy" means a licensed facility that compounds radiopharmaceuticals using positron emitting isotopes for use at licensed medical facilities.

(~~2930~~) "PET cyclotron facility" means a facility that manufactures short-lived radioisotopes for use in compounding radiopharmaceuticals at a PET Isotope Nuclear Pharmacy.

(~~304~~) "PET Medical Facility" means a clinical nuclear medicine facility that utilizes positron-emitting isotopes for diagnostic imaging.

(~~312~~) "Pharmacist" means an individual licensed by a state or territory of the United States, The District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

(~~323~~) "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

(~~334~~) "Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(~~345~~) "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

(~~356~~) "Positron Emission Tomography (PET) facility" means a facility comprised of an accelerator that produces positron-emitting isotopes, a radiopharmacy that specializes in preparation of PET radiopharmaceuticals, and/or a clinic that uses PET isotopes for medical diagnostic purposes.

(~~367~~) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer. The preceptor must have previously met all of the applicable requirements and be so named on a radioactive materials license issued by the Authority, the Nuclear Regulatory Commission, an Agreement State or licensing state.

(~~378~~) "Prescribed dosage" means the specified activity or range of activity of a radiopharmaceutical or radioisotope as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(~~389~~) "Prescribed dose" means:

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive;

(c) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(d) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

~~(3940)~~ "Pulsed dose-rate remote afterloader" means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose rate" range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

~~(404)~~ "Radiation Safety Officer" means an individual who:

(a) Meets the requirements in OAR 333-116-0640, 333-116-0650, 333-116-0740 and 333-116-0760; or

(b) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

(B) A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

~~(412)~~ "Recordable Event" (See Medical Event ~~and Misadministration~~).

~~(423)~~ "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~(434)~~ "Stereotactic Radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

~~(445)~~ "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

~~(456)~~ "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

~~(467)~~ "Teletherapy physicist" means the individual identified as the qualified teletherapy physicist on an Authority license.

~~(478)~~ "Therapeutic Dosage" means a dosage of unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

~~(489)~~ "Therapeutic Dose" means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

~~(4950)~~ "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

~~(504)~~ "Unit dosage" means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed by the Authority as a nuclear pharmacy.

~~(512)~~ "Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

~~(523)~~ "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in OAR 333-116-0125(1)(e), containing the following information:

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

(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(c) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

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

- (e) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
 - (f) For all other brachytherapy:
 - (A) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (B) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
- Stat. Auth.: ORS 453.635
Stats. Implemented: ORS 453.605 - 453.807
Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

333-116-0125

Quality Management Program

(1) Each applicant or licensee under this division, as applicable, must establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

- (a) That, prior to administration, a written directive (see NOTE below) is prepared for:
 - (A) Any teletherapy radiation dose;
 - (B) Any gamma stereotactic radiosurgery radiation dose;
 - (C) Any brachytherapy radiation dose;
 - (D) Any administration of quantities greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-125 or I-131; or
 - (E) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;
- (b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;
- (c) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
- (d) That each administration is in accordance with the written directive; and
- (e) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented

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immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(2) The licensee shall:

(a) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(A) A representative sample of patient administrations,

(B) All recordable events, and

(C) All ~~misadministrations~~ medical events to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(b) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subsection (2)(a) of this rule; and

(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(a) Assembling the relevant facts including the cause;

(b) Identifying what, if any, corrective action is required to prevent recurrence; and

(c) Retaining a record, in an auditable form, for five years or until inspected by the Authority, of the relevant facts and what corrective action, if any, was taken.

(4) The licensee shall retain:

(a) Each written directive; and

(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in subsection (1)(a) of this rule, in an auditable form, for five years, or until inspected by the Authority, after the date of administration.

(5) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Authority within 30 days after the modification has been made.

(6) Each applicant for a new license, as applicable, shall submit to the Authority in accordance with OAR 333-102-0190 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Authority.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1995, f. & cert. ef. 4-26-95; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-0130

Records and Reports of Misadministrations

~~((1) For a misadministration that meets the definition in OAR 333-116-0020 a licensee must:~~

~~(a) Notify the Authority by telephone no later than the next calendar day after discovery of the misadministration and provide information as outlined in paragraphs (b)(A) through (b)(H) of this section.~~

~~NOTE: The 24-hour phone number of the Authority is (971) 673-0490.~~

~~(b) Submit a written report to the Authority within 15 days after the discovery of the misadministration. The written report must include:~~

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- (A) The licensee's name;
 - (B) The prescribing physician's name;
 - (C) A brief description of the event to include:
 - ~~(i) Prescribed dose; and~~
 - ~~(ii) Delivered dose.~~
 - ~~(D) Why the event occurred;~~
 - ~~(E) The effect on the patient;~~
 - ~~(F) What improvements are needed to prevent recurrence;~~
 - ~~(G) Actions taken to prevent recurrence; and~~
 - ~~(H) Certification that the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.~~
 - ~~(e) The licensee must notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee must notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee must not delay medical care for the patient because of this.~~
 - ~~(d) If the patient was notified, the licensee also must furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:~~
 - ~~(A) A copy of the report that was submitted to the Authority; or~~
 - ~~(B) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Authority can be obtained from the licensee.~~
 - ~~(2) Each licensee must retain a record of each misadministration in accordance with OAR 333-100-0057. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.~~
 - ~~(3) Aside from the notification requirement, nothing in this rule must affect any rights or duties of licensees and physicians in relation to each other, patients or responsible relatives or guardians.~~
- ~~Stat. Auth.: ORS 453.635~~
~~Stats. Implemented: ORS 453.605—453.807~~
~~Hist.: HD 1-1991, f. & cert. ef. 1-8-91; HD 1-1995, f. & cert. ef. 4-26-95; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 32-2014, f. 12-22-14, cert. ef. 1-1-15~~

Imaging and Localization

333-116-0640

Radiation Safety Officer Training and Experience Requirements

Except as provided in OAR 333-116-0740, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in OAR 333-116-0090 to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in sections (4) and (5) of this rule. (The names of board certifications which have been recognized by the Commission 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)(A) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(B) Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

(C) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b)(A) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(B) Have two years of full-time practical training and supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and therapeutic services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0670, 333-116-0680 or 333-116-0740;

(C) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(2) Has completed a structured educational program consisting of 200 hours of classroom and laboratory training as follows:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

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

(d) Radiation biology;

(e) Radiopharmaceutical chemistry;

(f) Radiation dosimetry; and

(g) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Authority, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes similar type(s) of medical use of radioactive material involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

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

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of radioactive material; or

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under OAR 333-116-0905(1) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in sections (4) and (5) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(4) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in section (5) and in paragraphs (1)(a)(A) and (1)(b)(B) or paragraphs (1)(b)(A) and (1)(b)(B) or section (2), or subsections (3)(a) or (3)(b) of this rule, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0720

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Except as provided in OAR 333-116-0740, the licensee must require the authorized user of a sealed source specified in OAR 333-116-0480 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission (NRC) or an Agreement State and who meets the requirements in subsection (2)(c) and section (3) of this rule. (The names of board certifications which have been recognized by the Commission 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 therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(2) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit:

(a) Which includes the following:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(B) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(i) Reviewing full calibration measurements and periodic spot-checks;

(ii) Preparing treatment plans and calculating treatment doses and times;

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

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(v) Checking and using survey meters; and

(vi) Selecting the proper dose and how it is to be administered; and

(b) Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (2)(a)(B) of this rule; and

(c) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) or (2)(a) and (2)(b), and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in OAR 333-116-0720, 333-116-0740 or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(3) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: HD 1-1991, f. & cert. ef. 1-8-91; PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0905

Training for Authorized Medical Physicist

Except as provided in OAR 333-116-0740, the licensee shall require the authorized medical physicist to be an individual who:

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) and section (3) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(b) Have two years of full-time practical training and supervised experience in medical physics:

(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or

(B) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in OAR 333-116-0740, 333-116-0690 or 333-116-0720; and

(c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(2) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

(a) This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and must include:

(A) Performing sealed source leak tests and inventories;

(B) Performing decay corrections;

(C) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(D) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsections (1)(a) and (1)(b) of this rule, or subsection (2)(a) and section (3) of this rule, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is

requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this rule, OAR 333-116-0740, 333-116-0905, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08; PH 4-2010, f. & cert. ef. 2-16-10; PH 4-2013, f. & cert. ef. 1-29-13

333-116-0910

Training for an Authorized Nuclear Pharmacist

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

(1) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in subsection (2)(b) of this rule. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Has completed 700 hours in a structured educational program consisting of both:

(A) 200 hours of classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

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

(v) Radiation biology; and

(B) Supervised practical experience in a nuclear pharmacy involving:

(i) Shipping, receiving, and performing related radiation surveys;

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- (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
- (iii) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
- (iv) Using administrative controls to avoid medical events in the administration of byproduct material; and
- (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- (b) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsections (1)(a), (1)(b), and (1)(c) or (2)(a) of this rule and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 3-2003, f. & cert. ef. 3-27-03; PH 31-2004(Temp), f. & cert. ef. 10-8-04 thru 4-5-05; PH 36-2004, f. & cert. ef. 12-1-04; PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 14-2008, f. & cert. ef. 9-15-08

333-116-1000

Report and Notification of a Medical Event

(1) A licensee must report any medical event as defined in OAR 333-116-0020(19), except for an event that results from patient intervention., ~~in which the administration of radioactive material or radiation from radioactive material results in:~~

- ~~(a) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and~~
- ~~(A) The total dose delivered differs from the prescribed dose by 20 percent or more;~~
- ~~(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or~~
- ~~(C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.~~
- ~~(b) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:~~
 - ~~(A) An administration of a wrong radiopharmaceutical drug containing radioactive material;~~
 - ~~(B) An administration of a radiopharmaceutical drug containing radioactive material by the wrong route of administration;~~
 - ~~(C) An administration of a dose or dosage to the wrong individual or human research subject;~~
 - ~~(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or~~
 - ~~(E) A leaking sealed source.~~
- ~~(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~
- ~~(2) A licensee must report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material~~

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~~results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.~~

(~~23~~) The licensee must notify by telephone the Authority no later than the next calendar day after discovery of the medical event.

(~~34~~) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.

(a) The written report must include:

(A) The licensee's name;

(B) The name of the prescribing physician;

(C) A brief description of the event;

(D) Why the event occurred;

(E) The effect, if any, on the individual(s) who received the administration;

(F) What actions, if any, have been taken or are planned to prevent recurrence; and

(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(~~45~~) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.

(~~56~~) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07; PH 10-2011, f. 9-30-11, cert. ef. 10-1-11

~~333-116-1010~~

~~Report and Notification of a Misadministration~~

~~(1) A licensee must report any misadministration that involves:~~

~~(a) A diagnostic radiopharmaceutical dosage greater than 1.11 megabecquerels (30 uCi) of either sodium iodide I-123, I-125 or I-131;~~

~~(A) Involving the wrong individual or wrong radiopharmaceutical; or~~

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

~~(B) When the administered dosage exceeds the prescribed dosage by more than 20 percent of the prescribed dosage.~~

~~(b) A diagnostic radiopharmaceutical dosage less than 1.11 megabecquerels (30 uCi) of either sodium iodide I-123, I-125 or I-131 involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage exceeds 1.33 megabecquerels (36 uCi)~~

~~(c) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131;~~

~~(A) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or~~

~~(B) When the administered dosage exceeds the prescribed dosage by more than 20 percent of the prescribed dosage.~~

~~(d) A gamma stereotactic radiosurgery radiation dose:~~

~~(A) Involving the wrong individual or wrong treatment site; or~~

~~(B) When the calculated total administered exceeds the total prescribed dose by more than 10 percent of the total prescribed dose.~~

~~(e) A teletherapy radiation dose:~~

~~(A) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;~~

~~(B) When the treatment consists of three or fewer fractions and the calculated total administered dose exceeds total prescribed dose by more than ten percent of the total prescribed dose;~~

~~(C) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or~~

~~(D) When the calculated total administered dose exceeds the total prescribed dose by more than 20 percent of the total prescribed dose.~~

~~(f) A brachytherapy radiation dose:~~

~~(A) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or~~

~~(B) Involving a sealed source that is leaking;~~

~~(C) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or~~

~~(D) When the calculated administered dose exceeds the prescribed dose by more than 20 percent of the prescribed dose.~~

~~(2) The licensee must notify by telephone the Authority no later than the next calendar day after discovery of the medical event.~~

~~(3) The licensee must submit a written report to the Authority within 15 days after discovery of the misadministration.~~

~~(a) The written report must include:~~

~~(A) The licensee's name;~~

~~(B) The name of the prescribing physician;~~

~~(C) A brief description of the event;~~

~~(D) Why the event occurred;~~

~~(E) The effect, if any, on the individual(s) who received the administration;~~

~~(F) What actions, if any, have been taken or are planned to prevent recurrence; and~~

~~(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.~~

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

~~(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.~~

~~Stat. Auth.: ORS 453.635~~

~~Stats. Implemented: ORS 453.605—453.807~~

~~Hist.: PH 12-2006, f. & cert. ef. 6-16-06; PH 4-2007, f. & cert. ef. 3-1-07~~

DIVISION 125

MATERIALS SAFETY AND SECURITY

Background Investigations and Access Control Program

333-125-0060

Initial Investigation

(1) Before allowing an individual unescorted access to materials and devices containing category 1 or category 2 radioactive materials, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter.

(2) The background investigation must include at a minimum:

(a) Fingerprinting and an FBI identification and criminal history records check in accordance with OAR 333-125-0075 through 333-125-0080;

(b) Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to verify that the applicant is who he or she claims to be. A licensee shall review official identification documents such as driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth and compare the documents to personal information data provided by the individual to identify any discrepancy in the information.

(A) Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with OAR 333-125-0090; and

(B) Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection.

(c) Employment history verification. Licensees shall complete employment and military history verification. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application.

(d) Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period.

(e) Character and reputation determination. Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this division must be limited to whether the individual has been and continues to be trustworthy and reliable.

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(A) The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual such as seeking references not supplied by the individual; and
(B) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at the least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness or inability in the record of investigation; and attempt to obtain the information from an alternate source.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Physical Protection Requirements During Use

333-125-0100

Security Program

(1) Applicability: Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements outlined in this rule through OAR 333-125-0155.

(a) An applicant for a new license and each licensee that becomes newly subject to the requirements of OAR 333-125-0~~100 020~~ through 333-125-0~~155 095~~ upon application for modification of its license shall implement the requirements of OAR 333-125-0~~100 020~~ through 333-125-0~~155 095~~ as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

(b) Any licensee that has not previously implemented the Security Orders or been subject to the provisions OAR 333-125-0100 through 333-125-0155 shall provide written notification to the Authority at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

(2) General performance objective: Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

(3) Program features: Each licensee's security program must include the program features, as appropriate, described in OAR 333-125-0105 through 333-125-0150.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

333-125-0120

Security Program, Protection of Information

(1) Except as provided in section (9) of this rule, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall secure from public disclosure and limit access to their security and implementation plans, and the list of individuals that have been approved for unescorted access.

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(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of the security and implementation plans.

(3) Before granting an individual access to the security plan or implementation plans, the licensee shall:

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

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

(a) The categories of individuals listed in OAR 333-125-0085(1)(a) through (m); or
(b) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in OAR 333-125-0060(2)(b) through (2)(~~e~~)(~~B~~) has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and allowed access to the security and implementation plans.

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

(7) When not in use, the licensee shall store its security and implementation plans in a manner to prevent unauthorized access. Information stored in non-removable electronic form must be password protected.

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

(a) A copy of the information protection procedures; and
(b) The list of individuals approved for access to the security plan or implementing procedures.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15

Physical Protection in Transit

333-125-0180

Advance Notification of Shipment of Category 1 Quantities of Radioactive Material

(1) As specified in sections (1) and (2) of this rule, each licensee shall provide advance notification to the ~~Authority~~~~NRC~~ and the Governor of a state, or the Governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

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- (a) Procedures for submitting advance notification. The notification must be made to the NRC Authority and to the office of each appropriate Governor or Governor's designee. The contact information, including telephone and mailing addresses, of Governors and Governors' designees, is available on the NRC's website at <https://scp.nrc.gov/special/designee.pdf>. ~~<http://nrc-stp.ornl.gov/special/designee.pdf>~~. A list of the contact information is also available upon request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001. ~~Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by e-mail to RAMQC_SHIPMENTS@nrc.gov or by facsimile to (301) 816-5151.~~
- (b) A notification delivered by mail must be postmarked at least seven days before transport of the shipment commences at the shipping facility.
- (c) A notification delivered by any means other than mail must reach NRC at least four days before the transport of the shipment commences and must reach the office of the Governor or the Governor's designee at least four days before transport of a shipment within or through the state.
- (2) Information to be furnished in advance notification of shipment. Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:
- (a) The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;
- (b) The license numbers of the shipper and receiver;
- (c) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;
- (d) The point of origin of the shipment and the estimated time and date that shipment will commence;
- (e) The estimated time and date that the shipment is expected to enter each state along the route;
- (f) The estimated time and date of arrival of the shipment at the destination; and
- (g) A point of contact, with a telephone number, for current shipment information.
- (3)(a) Revision notice. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the Governor of the state or the Governor's designee and to the Authority, the NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- (b) A licensee shall promptly notify the Governor of the state or the Governor's designee of any changes to the information provided in accordance with sections (2) and (3) of this rule. The licensee shall also immediately notify the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 of any such changes.
- (4) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the Governor of each state or to the Governor's designee previously notified and to the ~~Authority, NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001~~. The licensee shall send the cancellation notice before the shipment

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has commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(5) Records. The licensee shall retain a copy of the advance notification, any revision and cancellation notices as a record for three years after the notification has been made.

(6) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the U.S Nuclear Regulatory Commission or an Agreement State, who receive schedule information of the kind specified in section (2) of this rule shall protect that information against unauthorized disclosure.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.635

Hist.: PH 19-2015, f. 9-30-15, cert. ef. 10-1-15