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

DIVISION 102

LICENSING OF RADIOACTIVE MATERIAL

333-102-0203

Definitions

The following definitions apply for Radioactive Material Licenses issued pursuant to this division and divisions 105, 113, 115, 117, and 121 of this chapter:

NOTE: Unless otherwise specified in this rule, the licenses described in this rule are limited by conditions of the radioactive materials license issued pursuant to OAR 333-102-0200, and other applicable rules in this chapter.

(1) "Analytical Leak Test" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(a), authorizing possession of environmental samples, sealed source leak-test, contamination wipe, ~~etc.~~ and samples for radioanalytical measurements. This license does not authorize collection of samples, or decommissioning or decontamination activities.

(2) "Assets" means anything of material value or usefulness. In the context of a materials license, assets include all existing capital, effects, possessions, and belongings and all probable future economic benefits obtained or controlled by a particular entity.

(3) "Basic License" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing the receipt, possession, use, transfer, and disposal of sources of radiation or radioactive materials incident to gauge service, teletherapy service, medical afterloader service, and other licensed service activities; pre-packaged waste pickup (not packaging), storage of materials prior to license termination, instrument quality control servicing or calibration (excluding activities authorized by 333-103-0010(2)(m)), or other minor activities not otherwise specified in these rules, such as authorization for "systems," as defined in these rules, pursuant to that definition.

(4) "Beneficiating" means subjecting a product to any process that can increase or concentrate any component (including the radioactive materials) to benefit the product.

(5) "Brachytherapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(c) authorizing the use of brachytherapy sources for in vivo application of radiation in accordance with 333-116-0420. Brachytherapy includes

radioactive material sealed sources in seeds, needles, plaques, or other localized medical devices, but excludes remote afterloaders.

(6) "Broad Scope A" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(d), authorizing activities in 333-102-0900(1)(a), under the authority of a Radiation Safety Committee.

(7) "Broad Scope B" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(e) authorizing activities described in 333-102-0900(1)(b), under the authority of a Radiation Safety Officer.

(8) "Broad Scope C" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(f) authorizing activities described in 333-102-0900(1)(c), under the authority of an authorized user.

(9) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety. ~~any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that can adversely affect the natural environment of a site.~~

(10) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this division that are related to radiological safety or security. The term "construction" does not include:

(a) Changes for temporary use of the land for public recreational purposes;

(b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this division;

(e) Excavation;

(f) Erection of support buildings (for example, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(g) Building of service facilities (for example, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) Taking any other action that has no reasonable nexus to radiological health and safety.

(119) "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

(124) "Decontamination and Decommissioning" means:

(a) A facility specific license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that result in returning a site to its original pre-license condition prior to termination of licensed activities; and

(b) Activities performed pursuant to OAR 333-102-0335 on any portion of a site prior to license termination.

(132) "Diagnosis" means examination, determination, identification, study, or analysis of a medical condition.

(143) "Distribution" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(g), authorizing transfer or distribution (sale) of general or specific license radioactive material to persons granted a general license or issued a specific license, or, in the case of NARM, to persons exempt from the rules in this chapter.

(154) "Exempt Source" means radioactive material, exempt from the rules in this chapter.

(165) "Facility" means location of licensed activities under the direct control of licensee management. If a "facility," as used in this division, includes multiple separate addresses, the Authority may determine how the scope of licensed activities, pursuant to OAR 333-102-0190, 333-102-0300, 333-102-0305, 333-102-0315, 333-102-0320, or 333-102-0325, is authorized.

(176) "Fixed Gauge" means a source-specific license for measuring, gauging, or controlling devices pursuant to OAR 333-103-0010(2)(h). The fixed gauge license also includes X-ray & Hybrid Gauges pursuant to division 115 of this chapter, that contain either an X-ray source or a radioactive sealed source.

(187) "General License" means a granted license, as opposed to an issued license, effective under these rules, to acquire, own, possess, use, or transfer radioactive material or a device that contains radioactive material.

- | (198) "General License Depleted Uranium" means the general license granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for depleted uranium used for shielding or counter weights and issued pursuant to 333-102-0103.
- | (2019) "General License Device" means the general license for in vitro materials granted subject to receipt of the registration application pursuant to OAR 333-101-0007, and fee, pursuant to 333-103-0015, for measuring, gauging.
- | (210) "General License In Vitro Laboratory" means the general license granted by OAR 333-102-0130, subject to receipt of the registration application pursuant to 333-101-0007, and fee, pursuant to 333-103-0015, for in vitro materials granted a general license by 333-102-0130.
- | (224) "General License Source Material" means the general license granted for use and possession of source material pursuant to OAR 333-102-0101.
- | (232) "General License for Certain Devices and Equipment" means the general license granted for use and possession of devices consisting of not more than 500 microcuries of polonium-210 or not more than 50 millicuries of tritium (H-3) per device, pursuant to 10 CFR 31.3.
- | (243) "General License for Luminous Devices for Aircraft" means the general license granted for use and possession of devices containing not more than ten curies of tritium or not more than 300 millicuries of promethium-147.
- | (254) "General License for Ownership of Radioactive Material and Limits of Possession" means the general license granted to own material that is not necessarily possessed; conversely, material that is possessed is, by grant of general license, not necessarily owned, pursuant to the general license in OAR 333-102-0120.
- | (265) "General License for Calibration and Reference Sources" means the general license granted to possess not more than five microcuries (185 kBq) of americium-241, plutonium-238, plutonium-239, or radium-226, pursuant to the general license in OAR 333-102-0125.
- | (276) "General License for Ice Detection Devices" means the general license granted to possess not more than 50 microcuries (1.85 MBq) of strontium-90, pursuant to the general license in OAR 333-102-0135.
- | (287) "Generators and Kits" means "Imaging and Localization."
- | (298) "Healing Arts Specific License" means a specific license authorizing activities in division 116 of this chapter.

- | (~~3029~~) "High Doserate Remote Afterloader" means a source-specific license issued pursuant to OAR 333-103-0010(2)(i) authorizing the use of sources in accordance with 333-116-0475, which may be either mobile or stationary, and which deliver a doserate in excess of two Gray (200 rad) per hour at the point or surface where the dose is prescribed. A device may be designated as being high, medium, or pulsed dose remote afterloader or mobile high, medium, or pulsed doserate remote afterloader.
- | (~~310~~) "Hybrid Gauge" means a fixed gauging device that contains both a sealed source and an X-ray source, pursuant to division 115 of this chapter.
- | (~~324~~) "In Vitro Laboratory" means a Healing Arts facility-specific license, under management of a physician or Healing Arts specialist, issued pursuant to OAR 333-103-0010(2)(k) authorizing the use of prepackaged radioactive materials in quantities greater than those authorized by the General License granted by 333-102-0130(2).
- | (~~332~~) Imaging and Localization means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(j) authorizing the use of generators and kits for nuclear medicine imaging and localization in accordance with 333-116-0320 or positron emission tomography studies in accordance with 333-116-0800 through 333-116-0880.
- | (~~343~~) "Industrial Radiography" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(l) authorizing activities in division 105 of this chapter.
- | (~~354~~) "Instrument Calibration" means a source-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(m) for sources of radiation used to calibrate instruments.
- | (~~365~~) "Investigational New Drug" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(n) authorizing the use of any investigational product or device approved by the US Food and Drug Administration (FDA) for human use research, diagnosis, or therapy, in accordance with the rules in this chapter.
- | (~~376~~) "Irradiator-Other" means an irradiator with greater than 10,000 curies (370 TBq) licensed pursuant to OAR 333-103-0010(2)(w) and 333-103-0010(7), designed to produce extremely high dose rates as authorized by division 121 of this chapter.
- | (~~387~~) "Irradiator Self-shielded or Other -- Less than 10,000 Curies" means a source-specific license issued pursuant to OAR 333-103-0010(2)(o) authorizing self-shielded irradiators, including blood irradiators, panoramic irradiators, and converted teletherapy units, with less than 10,000 Ci (370 TBq) activity.
- | (~~398~~) "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

- | (~~4039~~) "Lot Tolerance Percent Defective" means, expressed in percent defective, the poorest quality in an individual inspection lot that can be accepted.
- | (~~410~~) "Low Doserate Remote Afterloader Device" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(b) authorizing devices 333-116-0475, which remotely deliver a doserate of less than two Gray (200 rad) per hour at the point or surface where the dose is prescribed.
- | (~~424~~) "Manufacturing or Compounding" means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(p) authorizing manufacture, fabrication, assembly, construction, combining, processing, concentrating, beneficiating, or processing items or products using or containing radioactive materials into a finished product containing radioactive material in accordance with applicable requirements in division 102 of this chapter.
- | (~~432~~) "Manufacturing or Compounding and Distribution" means activities performed as defined in sections (~~143~~) and (~~424~~) of this rule and require separate specific licenses for each activity.
- | (~~443~~) "Mobile Nuclear Medicine Service" means a facility-specific Healing Arts license issued pursuant to OAR 333-116-0120 authorizing the medical use of radioactive material at specified temporary locations.
- | (~~454~~) "~~"~~Nationally Tracked Source~~"~~" means a sealed source containing a quantity equal to or greater than Category 1 or 2 levels of any radioactive material listed in 10 CFR 20 Appendix E.
- | (~~465~~) "Naturally occurring radioactive material (NORM)" means radioactive material in the uranium or thorium decay series existing in nature in concentrations less than 0.05 percent source material.
- | (~~476~~) "Net working capital" means current assets minus current liabilities.
- | (~~487~~) "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.
- | (~~498~~) "Neutron Howitzer" means a device that contains a sealed source containing Special Nuclear Material (see definition in OAR 333-100-0005) that generates neutrons that are used for analytical, teaching, or research purposes.
- | (~~5049~~) "Neutron Production" denotes a process in which neutrons are produced, either by natural or artificial means.
- | (~~510~~) "NORM (no processing)" means a facility-specific license pursuant to OAR 333-103-0010(2)(r) authorizing possession, use, and transfer of NORM in accordance with division 117 of this chapter.

NOTE: NORM licenses authorize licensable quantities of radioactive material in the uranium or thorium decay series. Licensable quantities of NORM are derived from disposal limits in OAR chapter 345, division 050. Any material that contains NORM requires a specific license unless exempted in OAR chapter 345, division 050. Zircon sand is used as the NORM model for licensing purposes. Quantities of zircon sand in excess of 20,000 pounds in a year constitute a licensable quantity of NORM. NORM materials that are not zircon are based on the zircon model.

| (524) "Nuclear Laundry" means a laundry facility designed specifically to clean or launder clothing contaminated with licensed radioactive materials. Nuclear Laundry facilities must have process and waste management control procedures to prevent reconcentrating of licensed materials in sewers, drains, premises, and the environment. Nuclear Laundry activities are authorized pursuant to OAR 333-103-0010(2)(w), "Radioactive Material Not Otherwise Specified Facility," see 333-102-0203(61).

| (532) "Nuclear Pharmacy" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(s) for activities authorized by 333-102-0285 and the Oregon Board of Pharmacy rules, to compound Radiopharmaceutical and distribute (sell or transfer) to persons specifically licensed to receive such compounds or products.

NOTE: Nuclear Pharmacies, pursuant to policy provisions of chapter 345 division 50 may collect syringes containing residual licensed material from spent patient doses, since the syringe is considered to be a transport device under the administrative control of the pharmacy rather than the licensed material transferred as the dose. Residual licensed material may be considered either to be exempt pursuant to Table 1 of division 50 or under the authority of a division license if the receding licensee stores syringes for decay. In either case, the division license specifies which disposal method is being used by the pharmacy and licensee to avoid compatibility conflicts with division 50 requirements.

| (543) "Other Measuring Device" means a source-specific license issued pursuant to OAR 333-103-0010(2)(t), authorizing analytical instruments, gas chromatograph electron capture detectors, and other non-portable analytical instruments, including those devices that contain multiple sources but are configured and used as a "system," in accordance with the definition in this rule.

NOTE: General license gas chromatograph detectors that formerly were granted a general license by OAR 333-102-0115, but which required a registration fee pursuant 333-103-0015(2)(b), now are subject to the specific license in 333-103-0010(2)(t).

| (554) "Pool-type Irradiator" means an irradiator with greater than 10,000 curies (370 TBq) in which water provides the radiation shielding, authorized in accordance with division 121 of this chapter.

| (565) "Portable Gauge" means a source-specific license issued pursuant to OAR 333-103-0010(2)(u) for sources used in devices that can be transported and used at temporary job sites.

NOTE: Any device that meets the definition of "portable gauge" and is transported or used at temporary job sites within the state of Oregon, requires an application for and issuance of an Oregon specific license subject to OAR 333-103-0010(2)(u).

- | (576) "Positron Emission Tomography" (PET) means a licensed healing arts activity authorized by OAR 333-116-0800 and included in the facility specific license issued pursuant to 333-103-0010(2)(j). PET nuclides, which are NARM, are subject to all Oregon rules.
- | (587) "Possession or Storage of Industrial Wastes Containing Radioactive Material" means activities subject to division 110 of this chapter for the production or storage of wastes that are exempt from division 50 of chapter 345 facility siting requirements, and were generated under a current NRC, Agreement State, or Licensing State specific radioactive materials license.
- | (598) "Possession or Storage of Uranium Tailings" means activities incident to uranium processing or milling operations resulting in the production of tailings.
- | (6059) "Principal Activities" means activities authorized by the license that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- | (610) "Processing" means chemically or physically changing a licensed material from one physical form to another form or specie (for example.g., breaking an ore down into its components resulting in "tailings"; milling a raw licensed material and combining to form another product or material. See "Beneficiating"; "Manufacturing or Compounding").
- | (624) "Radiation Source" means source of radiation (see definition of "Source of radiation" in OAR 333-100-0005).
- | (632) "Radioactive Material Not Otherwise Specified Facility" means a license issued pursuant to OAR 333-103-0010(2)(w) authorizing activities that includes, but are not limited to, complex licensable activities such as facility decontamination and decommissioning, nuclear laundry activities, uranium mill tailings storage, storage of industrial wastes containing radioactive materials, large irradiator management, and other complex activities not otherwise specified in these rules.
- | (643) "Radioactive Materials License" means the document, pursuant to OAR 333-102-0300, issued after an application, pursuant to OAR 333-102-0190, has been accepted as adequate, that specifies radioactive materials, use authorizations, safety procedures, and use locations.
- | (654) "Radiopharmaceutical Therapy" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(v) authorizing the use of Radiopharmaceutical for therapy in accordance with 333-116-0360.

(665) "Remote Afterloader" means a medical device that moves a sealed source to an interstitial (in vivo) location without exposing the practitioner to the radiation dose. Remote afterloader sources may be manipulated using computer software and engineering techniques.

(676) "Research & Development" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(x) authorizing research and development activities, as defined in 333-100-0005, but does not authorize additional specific sources of radiation, which must be licensed separately pursuant to 333-103-0010 and 333-103-0015.

(687) "Responsible Representative" means

(a) The person designated as having responsibility for general license device or general license material;

(b) The person management has selected to certify general license inventory; and

(c) The individual responsible to the Authority and to management to ensure that all regulatory elements are adequate.

(698) "Sealed Source/Device Evaluation" means the review of a licensee's prototype source or device prior to registration by the Nuclear Regulatory Commission in the Sealed Source and Device Catalog.

NOTE: The Authority no longer has authority to review sources or devices. All source or device reviews must be forwarded to the NRC for review. Authority to conduct device or source evaluations was rescinded by the NRC in 1998.

(7069) "Site Area Emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

(710) "Sealed Sources for Diagnosis" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(y) authorizing the use of sealed sources for diagnosis in accordance with 333-116-0400.

(724) "Special Nuclear Material" means:

(a) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or

(b) Any material artificially enriched by any of the foregoing but does not include source material.

| (732) "Specific License Radioactive Material" means radioactive material that requires authorization in a specific license document pursuant to OAR 333-102-0075(2) where materials must be annotated on the specific license, and validated with a specific license fee pursuant to 333-103-0010(2)(a) through 333-103-0010(2)(hh) (see "Radioactive Materials License").

| (743) "System," as used in this division, means multiple separate (individual) sources of radiation (sealed radioactive sources), which together, rather than independently, achieve a desired functionality. Such "system" is subject to one specific license fee or general license registration fee, as the case may be.

| (754) "Tangible Net Worth" means the tangible assets that remain after deducting liabilities; such assets may not include intangibles such as goodwill and rights to patents or royalties.

| (765) "Teletherapy" means a Healing Arts source-specific license issued pursuant to OAR 333-103-0010(2)(cc) authorizing teletherapy procedures in accordance with OAR 333-116-0480. This license also includes other high dose rate external beam therapy devices such as the "gamma knife."

| (776) "Temporary Job Site" means any location, where specific license material is used that is either:

(a) Not the specific location of the licensee if an in-state licensee; or

(b) Any location in the state if an out-of-state specific licensee pursuant to a specific radioactive materials license.

NOTE: Persons authorized for temporary jobsites in Oregon must have a specific license for such activities.

| (787) "Therapy" means a process that is meant to be restorative, promotes healing, or is beneficial to a patient in a healing arts context.

| (798) "Unique" means a specific license issued pursuant to OAR 333-103-0010(2)(dd) to agencies in the Oregon Health Authority.

| (8079) "Uptake and Dilution" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ee) authorizing activities in 333-116-0300 for uptake, dilution, and excretion studies.

| (819) "Use and Possession of Source Material " means a facility-specific radioactive materials license issued pursuant to OAR 333-103-0010(2)(z) to possess, use, process, or transfer source material, as defined in OAR 333-100-0005, in quantities greater than general license quantities or in concentrations greater than 0.05 percent source material.

NOTE: This definition was amended to avoid confusion between the definition of "source material" in division 100 of this chapter and the specific license (billable object) in division 103 of this chapter.

| (8~~24~~) "Use of Xenon Gas" means a Healing Arts facility-specific license issued pursuant to OAR 333-103-0010(2)(ff) authorizing the use of Xe-133 for diagnosis pursuant to OAR 333-116-0280.

| (8~~32~~) "Waste Packaging" means a facility-specific license issued pursuant to OAR 333-103-0010(2)(gg), authorizing packaging, collection, storage, and transfer of radioactive waste. This specific license does not authorize storage of radioactive wastes, but does authorize temporary job sites.

| (8~~43~~) "Well Logging" means a license issued pursuant to OAR 333-103-0010(2)(hh) authorizing the possession, use, transfer, or disposal of sources of radiation used for well logging activities authorized by division 113 of this chapter.

NOTE: Unless specifically authorized in this rule or in a radioactive materials license that authorizes temporary job sites, specific licenses must be used only at one authorized site.

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

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

333-102-0305

Specific Terms and Conditions of License

(1) Each license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120, 121 and 124 of this chapter are subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations and orders of the Authority.

(2) No license issued or granted pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter nor any right may be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Authority, after securing full information, shall find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

(3) An application for transfer of license must include:

(a) The identity, technical and financial qualification of the proposed transferee; and

(b) Financial assurance for decommissioning as required by OAR 333-102-0200(6)

(43) Each person licensed by the Authority pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter must confine the use and possession of the radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be in accordance with the provisions of division 118 of this chapter.

(54) Each license issued pursuant to the rules in this division and divisions 105, 113, 115, 116, 117, and 121 of this chapter shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Atomic Energy Act of 1954, as amended, whether or not these provisions are expressly set forth in the license.

(65) The Authority may incorporate, in any license issued pursuant to the rules in this division and divisions 103, 105, 113, 115, 116, 117, 120 and 121 of this chapter, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:

(a) Promote the common defense and security;

(b) Protect health or to minimize danger to life or property;

(c) Protect restricted data; and

(d) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(76) Licensees required to submit emergency plans by OAR 333-102-0190(10) must follow the emergency plan approved by the Authority. The licensee may change the approved plan without Authority approval only if the changes do not decrease the effectiveness of the plan. The licensee must furnish the change to the Authority and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Authority.

(87) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85, respectively, in accordance with OAR 333-116-0330. The licensee must

record the results of each test and retain each record for three years after the record is made.

(98)(a) Each general licensee subject to the registration requirement in OAR 333-101-0007 and each specific licensee must notify the Authority in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(A) The licensee;

(B) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(b) This notification must indicate:

(A) The bankruptcy court in which the petition for bankruptcy was filed; and

(B) The date of the filing of the petition.

(109) Sealed sources or detector cells containing licensed material must not be opened or sources removed from source holders or detector cells by the licensee.

(110) No licensee may acquire licensed radioactive material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

(124) Any sealed source fabricated by a licensee must be registered, inspected, and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source in accordance with requirements in 10 CFR 32.210.

(132) Each licensee must conduct a physical inventory at intervals not to exceed six months to account for all radioactive material received and possessed by licensee. Inventories must include the types and quantities of radioactive material, location of materials, date of receipt, and the date of the inventory; and for sealed sources, the inventory must include the types and quantities of sealed sources, sealed source manufacturer, model number, serial number, date of receipt, condition of sealed sources, and the date of the inventory. Records of the inventories required by this section ~~(12) of this rule~~ must be kept until inspection by the Authority.

(143) Each licensee must transport radioactive material or deliver radioactive material to a carrier for transport in accordance with the provisions of Parts 170 through 189 of Title 49, Code of Federal Regulations and in accordance with division 118 of this chapter, "Transportation of Radioactive Material."

- | (154) Each licensee possessing a device licensed pursuant to OAR 333-103-0010(2)(h) must perform an inspection of all devices at intervals not to exceed six months. Inspections must include condition of labeling and posting of each radiation device, and corrective actions taken if any; condition of shutter operation, if applicable, of each device, and corrective actions taken if any; and location of each device. Records of the inspections required by [this section](#) ~~(14) of this rule~~ must be kept until inspection by the Authority.
- | (165) No licensee may open or remove radioactive material from sealed sources or detector cells containing licensed radiation sources.
- | (176) No person may repair, modify, dismantle, or effect any change in licensed devices or radiation sources, nor modify nor alter labels affixed to licensed devices by the manufacturer
- | (187) Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of fixed gauging devices containing radioactive sealed sources, and installation, replacement, and disposal of sealed sources must be performed only by persons specifically authorized by the Authority, the U.S. Nuclear Regulatory Commission, or another Agreement state to perform such services. Records of all surveys must be maintained for inspection by the Radiation Protection Services section.
- | (198) If the licensee has previously determined that monitoring for internal exposure pursuant to OAR 333-120-0130, 333-120-0210, or 333-120-0320 is required, the data and results of this evaluation must be placed in the worker's exposure records and included the worker's Oregon Form Z report.
- | (2049) Testing for leakage or contamination of sealed sources must be in accordance with requirements in OAR 333-120-0460. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person must not be put into use until tested.
- | (219) Detector cells must be used only in conjunction with a properly operating temperature control mechanism that prevents foil temperatures from exceeding manufacturer's specifications. Exhaust from detector cells must be vented to keep exposures to personnel and the public as low as reasonably achievable pursuant to OAR 333-120-0180.
- | (224) Licensees who possess sealed sources used for testing at field sites must possess at such locations transport documents, a current copy of the specific radioactive materials license, specific license validation certificates, the current leak test certificate, and the licensee's operating and emergency procedures. Licensed materials stored in an unrestricted area must be secured from unauthorized removal from the place of storage in accordance with provisions of OAR 333-120-0250 and 333-120-0260.

- | (232) Any specific licensee is authorized to receive, possess, use, transfer, and import up to 999 kilograms of uranium contained as shielding for specific licensed radioactive material authorized by license.
- | (243) A licensee may store, pursuant to OAR 333-120-0500, radioactive waste for decay in storage before disposal in accordance with OAR 333-116-0290.
- | (254) Licensed materials in an unrestricted area and not in storage must be tended under the constant surveillance and immediate control of the licensee.
- | (265) Except as otherwise specified in a radioactive materials license, the licensee must have available and follow the instructions contained in the manufacturer's instruction manual for the chromatography device.
- | (276) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in OAR 333-120-0400(2), the licensee is hereby authorized to label detector cells and cell baths, containing licensed radioactive material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
- | (287) If a radiography licensee plans to use, during normal industrial radiographic operations subject to division 105 of this chapter, two or more exposure devices at one jobsite, the licensee must require at least one Radiographer or Radiographer Instructor authorized user for each exposure device, and the total number of authorized personnel (radiographers and assistant radiographers) at the temporary jobsite must not be less than $n+1$ where n =the number of cameras.
- | (298) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of two independent physical controls that form two separate tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.
- | (3029) Authorization under OAR 333-102-0190(10)(c)(N) to produce Positron Emission Tomography (PET) radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceutical drugs.
- | (319) Each licensee authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall:
 - (a) Satisfy the labeling requirements in OAR 333-102-0285(1)(d) for each PET radiopharmaceutical drug transport radiation shield and each syringe, vial, or other container used to hold a PET radiopharmaceutical drug intended for noncommercial distribution to members of its consortium.

(b) Possess and use instrumentation to measure the radioactivity of the PET radiopharmaceutical drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in OAR 333-102-0285(3).

| (3~~2~~4) A licensee that is a pharmacy authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radiopharmaceutical drugs shall be:

(a) An authorized nuclear pharmacist who meets the requirements in OAR 333-116-0910; or

(b) An individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.

| (3~~3~~2) A pharmacy, authorized under OAR 333-102-0190(10)(c)(N) to produce PET radiopharmaceutical drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of OAR 333-116-0910.

Stat. Auth.: ORS 453.635, 453.665

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 106

X-RAYS IN THE HEALING ARTS

333-106-0005

Definitions

As used in this division, the following definitions apply:

(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) "Direct supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) shall be present in the room while the individual operates the equipment.~~

~~(345)~~ "Entrance Exposure Rate" means the exposure free in air per unit of time.

~~(356)~~ "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.

~~(367)~~ "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

~~(378)~~ "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.

~~(389)~~ "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.

~~(3940)~~ "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~~~~i.e.~~ veterinarian human holders) are excluded from this rule.

~~(404)~~ "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.

~~(412)~~ "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.

~~(43) "General supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s), must be immediately available by telephone, pager, or other mode of communication, to provide direction if needed or requested.~~

~~(424)~~ "Gonad Shield" means a protective barrier for the testes or ovaries.

(435) "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.

(446) "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.

(457) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, example being: e., kVp x mA x second.

(468) "HVL" (see "Half-value layer").

(479) "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.

(4850) "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.

~~(51) "Indirect supervision" means that the person who directs the X-ray or fluoroscopic equipment operator(s) be readily available on facility premises when the X-ray or fluoroscopic equipment is operated.~~

(4952) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(503) "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.

(514) "Irradiation" means the exposure of matter to ionizing radiation.

(525) "Kilovolt-Peak" (see "Peak tube potential").

(536) "kV" means kilovolts.

(547) "kVp" (see "Peak tube potential").

(558) "kWs" means kilowatt second.

(569) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(~~5760~~) "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.

(~~5864~~) "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 i.e.,~~ 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.

(~~5962~~) "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.

(~~603~~) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.

(~~614~~) "mA" means milliampere.

(~~625~~) "mAs" means milliamperere second.

(~~636~~) "Maximum Line Current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

(~~647~~) "Mobile Equipment" (see "X-ray Equipment").

(~~658~~) "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 ~~and~~/or therapeutic use of X-rays; and
- (b) Are currently licensed by their respective Oregon licensing board.

(~~669~~) "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.

(~~677~~) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

(~~687~~) "Peak Tube Potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

(~~697~~) "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.

(~~703~~) "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").

(~~714~~) "PID" (see "Position indicating device").

(~~725~~) "Portable Equipment" (see "X-ray Equipment").

(~~736~~) "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.

(~~747~~) "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.

(~~758~~) "Primary Protective Barrier" (see "Protective barrier").

(~~769~~) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(~~778~~) "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.

| (784) "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.

| (7982) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

| (803) "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.

| (814) "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.

| (825) "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.

| (836) "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.

| (847) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.

| (858) "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

| (869) "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.

| (8790) "Radiologist" or "Oral Radiologist" means a physician or dentist trained in the diagnostic ~~and~~/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.

| (8894) "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.

(~~892~~) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Medical Imaging.

(~~903~~) "Rating" means the operating limits as specified by the component manufacturer.

(~~914~~) "Recording" means producing a permanent form of an image resulting from X-ray photons.

(~~925~~) "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.

(~~936~~) "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.

(~~947~~) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").

(~~958~~) "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.

(~~969~~) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.

(~~97400~~) "Secondary Protective Barrier" (see "Protective barrier").

(~~98404~~) "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.

(~~99402~~) "SID" (see "Source-image receptor distance").

(~~1003~~) "Source" means the focal spot of the X-ray tube.

(~~1014~~) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.

(~~1025~~) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.

(1036) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(1047) "Spot-Film Device" means a device intended to transport ~~and~~/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.

(1058) "SSD" means the distance between the source and the skin of the patient.

(1069) "Stationary Equipment" (see "X-ray Equipment").

(10749) "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.

(10944) "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.

(1102) "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.

(1113) "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.

(11~~24~~) "Tube" means an X-ray tube, unless otherwise specified.

(11~~35~~) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and ~~or~~ filament transformers and other appropriate elements when such are contained within the tube housing.

(11~~46~~) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(11~~57~~) "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.

(11~~68~~) "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.

(11~~749~~) "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.

(11~~820~~) "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.

(11~~924~~) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

(12~~02~~) "X-ray Control" means a device which controls input power to the X-ray high-voltage generator and ~~or~~ 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.

(12~~13~~) "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 ~~or~~ 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) "~~122~~" Hand-held unit" means a 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.

(~~1224~~) "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 "~~122~~" Operator").

(~~1235~~) "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.

(~~1246~~) "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.

(~~1257~~) "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.

(~~1268~~) "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.

(~~12729~~) "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

333-106-0025

Protection of Patients and Personnel

(1) Except for patients who cannot be moved out of the unprotected area, only the staff and ancillary personnel required for the medical procedure or training shall be in the unprotected area during the radiographic exposure. ~~Other than the patient being examined:~~

(42) ~~Other than the patient being examined,~~ All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter (mm) lead equivalent.

(23) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.

(34) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0040

Patient Holding and Restraint

(1) When a patient or film must be provided with auxiliary support during a radiation exposure:

(4a) Mechanical holding devices shall be provided and used when the technique permits. The safety rules, required by OAR 333-106-0020 ~~of these rules~~, shall list individual projections where holding devices cannot be used.

(2b) Written safety procedures, as required by OAR 333-106-0020 ~~of these rules~~, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(3c) The human holder shall be protected, as required by OAR 333-106-0025 ~~(1) and (2) of these rules~~.

(42) No individual shall be used routinely to hold film or patients.

(53) Occupationally exposed personnel are prohibited from holding human patients during radiographic examination.

(64) The Authority may require a separate record to be maintained which would include the name of the human holder, date of the examination, number of exposures and technique factor used for the exposure(s).

(75) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest exposed to the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

(86) Holding of patients shall be permitted only when it is otherwise impossible to obtain the necessary radiograph.

(97) Individuals stressing joints shall be exempt from section (35) of this rule.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0045

Use of Best Procedures and Equipment

(1) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. ~~This is interpreted to include, but is not limited to:~~

(42) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(23) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see Tables 1, 2 and 3. The referenced tables are available on the Program's website: www.healthoregon.org/rps.

(34) Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation due to the medical status of the patient or the inability of the patient to be left alone during the imaging procedure except as permitted under section (54) of this rule.

(45) Hand-held dental units may be used at facilities or programs as defined in ORS 680.205(1) and (2).

(56) X-ray systems subject to OAR 333-106-0301(4) shall not be utilized in procedures where the source to patient distance is less than 30 centimeters (cm).

(67) Cardboard cassettes without screens shall not be used (dental intraoral excluded).

| ~~(78)~~ The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the clinical condition.

| ~~(89)~~ Use of techniques designed to compensate for anatomical thickness variations after the primary beam has exited the patient is specifically prohibited. This includes "split screen" imaging techniques whereby multiple speed intensifying screens are placed in the same cassette, or any techniques which rely on attenuation of secondary (remnant) radiation for compensatory purposes. Lead lined grids, which are designed to reduce scattered radiation are excluded from this provision.

| ~~(910)~~ Filter slot covers shall be provided for the X-ray operator's protection.

| ~~(1011)~~ Facilities shall determine or cause to be measured the typical patient exposure for their most common radiographic examinations. The exposures shall be recorded as milliroentgens measured in free air at the point of skin entrance for an average patient. These exposure amounts must then be compared to existing guidelines and rules, and if they exceed such guidelines or rules, action must be taken to reduce the exposure while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted in the radiographic examination rooms so that they are readily available to administrators, X-ray operators, patients and practitioners.

| ~~(1112)~~ Protective equipment including aprons, gloves and shields shall be checked annually for defects, such as holes, cracks and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Authority. If such defect is found, equipment shall be replaced or removed from service until repaired. Fluoroscopy shall only be used for this purpose if a visual and manual check indicated a potential problem.

| ~~(1213)~~ Dental X-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.

| ~~(1314)~~ An X-ray quality control program shall be implemented when required by the Authority.

| ~~(1415)~~ All X-ray equipment must be capable of functioning at the manufacturer's intended specifications.

| ~~(1516)~~ All patients' radiographic images or copies shall be made available for review by any practitioner of the healing arts, currently licensed by the appropriate Oregon licensing board, upon request of the patient.

| ~~(16) Requirements for the operation of fluoroscopic X-ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:~~

| ~~(a) Radiologists;~~

~~(b) Non-Radiologist practitioners with proper training in the operation and use of fluoroscopic X-ray equipment;~~

~~(c) R.T.s, must be ARRT registered and in good standing with the Oregon Board of Medical Imaging.;~~

~~(d) R.P.A.s and R.R.A.s;~~

~~(e) Technologists, who have successfully completed an educational program in radiologic technology from an approved school as defined in ORS 688.405, may temporarily operate fluoroscopic equipment for up to one year as outlined in OAR 337-010-0045 while waiting to take the ARRT registry examination.~~

~~(A) The temporary period expires when the individual has passed the registry examination and is considered an R.T.;~~ or

~~(B) One year from the date when the technologist completed his/her training, provided; and~~

~~(C) The technologist, while in the temporary status referred to in subsection (16)(e) of this rule, has a current temporary license issued by the Oregon Board of Medical Imaging.;~~

~~(f) The operation of fluoroscopic equipment by R.T.s, or R.P.A.s or R.R.A.s shall be performed under the supervision of a radiologist and is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.~~

~~(g) Where direct or indirect supervision by a radiologist is impractical, a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic X-ray equipment is permitted to supervise an R.T. operating fluoroscopic equipment provided that the registrant arranges to have a radiologist or Medical or Health physicist to 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.~~

~~(h) The operation of fluoroscopic equipment by a R.T. is restricted to the healing arts exclusively for the purpose of localization and to assist physicians in obtaining images for diagnostic purposes.~~

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

~~(j) Students currently enrolled in an Authority approved R.P.A. or R.A. training program, may only operate fluoroscopic equipment under the direct or in-direct supervision of a Radiologist during their clinical phase of training.~~

~~(k) 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.~~

~~(l) Proper training in the operation of fluoroscopic X-ray equipment shall include but not be limited to the following:~~

~~(A) Principles and operation of the fluoroscopic X-ray machine;~~

~~(i) Generating X-rays;~~

~~(ii) kVp and mA;~~

~~(iii) Image intensification;~~

~~(iv) High level control versus standard operating mode;~~

~~(v) Magnification (multi field);~~

~~(vi) Automatic Brightness Control (ABC);~~

~~(vii) Pulsed versus Continuous X-ray Dose Rates;~~

~~(viii) Image recording modes;~~

~~(ix) Imaging Systems (TV and Digital);~~

~~(x) Contrast, noise and resolution;~~

~~(B) Radiation units;~~

~~(i) Traditional units;~~

~~(ii) SI units;~~

~~(iii) Dose Area Product;~~

~~(C) Typical fluoroscopic outputs;~~

~~(i) Patient skin entrance dose;~~

~~(ii) Standard Roentgen per minute (R/min) dose rates;~~

~~(iii) High level/Boost enable Roentgen per minute (R/min) dose rates;~~

~~(D) Dose reduction techniques for fluoroscopy;~~

~~(i) The use of collimation;~~

~~(ii) X-ray tube and Image intensifier placement;~~

~~(iii) Patient size versus Technique selection;~~

~~(iv) Use of grid;~~

~~(v) Use of last image hold;~~

~~(vi) Additional beam filtration;~~

~~(vii) Alternate gantry angles;~~

~~(viii) Use of spacer cone;~~

~~(ix) Pulsed fluoroscopy;~~

~~(E) Factors affecting personnel dose;~~

~~(i) Patient dose;~~

~~(ii) Scatter radiation;~~

~~(iii) Tube and Image intensifier placement;~~

~~(iv) Time, distance and shielding;~~

~~(F) Protective devices;~~

~~(i) Lead aprons and gloves;~~

~~(ii) Thyroid collars;~~

- ~~(iii) Protective glasses;~~
- ~~(iv) Leaded drapes;~~
- ~~(v) Bucky slot cover;~~
- ~~(vi) Protective shields/barriers;~~
- ~~(G) Radiation exposure monitoring;~~
 - ~~(i) Personnel monitors;~~
 - ~~(ii) Placement of personnel monitors;~~
 - ~~(iii) Occupational and non-occupational dose limits;~~
- ~~(H) Biological effects of X-ray radiation;~~
 - ~~(i) X-rays and particulate matter;~~
 - ~~(ii) Absorption variables (field size, dose rate, etc.);~~
 - ~~(iii) Scatter radiation;~~
 - ~~(iv) Cell sensitivity;~~
 - ~~(v) Acute effects;~~
 - ~~(vi) Latent effects;~~
- ~~(I) Applicable regulations;~~
 - ~~(i) Federal; and~~
 - ~~(ii) Oregon Rules for the Control of Radiation to include, but not limited to, divisions 101, 103, 106, 111 and 120.~~
- ~~(17) Radiologists, R.A.s or R.P.A.s and R.T.s currently licensed in Oregon are considered to have met the training requirements in subsection (16)(l) of this rule.~~
- ~~(18) Fluoroscopic equipment operators who qualified to operate fluoroscopic X-ray equipment prior to April 11, 2005, are considered as having met the training requirements in subsection (16)(l) of this rule.~~
- ~~(19) 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.As and R.P.As may issue a preliminary report, however, the final report must be issued by their supervising radiologist.

~~(20) 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 the direction of R.T.s who operate fluoroscopic equipment.~~

~~(21) 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.~~

~~(22) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patients name, the type of examination, the date of the examination, the fluoroscopists name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on time for each fluoroscopic examination and:~~

~~(a) No later than May 1, 2006, establish 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;~~

~~(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 ten 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, training, etc. in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.~~

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0055

X-ray Operator Training

(1) The registrant shall assure that individuals who will be operating the X-ray equipment by physically positioning patients or animals, determining exposure parameters, or applying radiation for diagnostic purposes shall have adequate training in radiation safety.

(a) Radiation safety training records shall be maintained by the registrant for each individual who operates X-ray equipment. Records must be legible and meet the requirements in OAR 333-120-0690.

(b) When requested by the Authority, radiation safety training records shall be made available.

~~(2) Adequate training in radiation safety means X-ray operators have completed an Authority approved radiation use and safety course. a minimum of 40 hours of didactic instruction for diagnostic medical X-ray equipment operators, eight hours for Grenz ray X-ray equipment operators and 20 hours for veterinary X-ray equipment operators from an~~

~~(3) At a minimum, an Authority approved training course shall covering the following subjects:~~

~~(a) Nature of X-rays;~~

~~(b) Interaction of X-rays with matter;~~

~~(c) Radiation units;~~

~~(d) Principles of the X-ray machine;~~

~~(e) Biological effects of X-ray;~~

~~(f) Principles of radiation protection;~~

~~(g) Low dose techniques;~~

~~(h) Applicable federal and state radiation regulations including those portions of divisions 100, 101, 103, 106, 111 and 120 of chapter 333;~~

~~(i) Darkroom and film processing;~~

~~(j) Film critique; and~~

~~(k) Animal restraint training (for veterinary technologists or assistants only).~~

~~**NOTE:** Subsections (1)(g), (1)(i), (1)(j) and (1)(k) of this rule are not required for Grenz ray X-ray equipment operator training.~~

~~(a) Nature of X-rays:~~

~~(A) Interaction of X-rays with matter ;~~

~~(B) Radiation units;~~

~~(C) X-ray production;~~

~~(D) Biological effects of X-rays; and~~

~~(E) Risks of radiation exposure.~~

(b) Principles of the X-ray machine:

(A) External structures and operating console;

(B) Internal structures:

(i) Anode; and

(ii) Cathode.

(C) Operation of an X-ray machine;

(D) Tube warm up;

(E) Factors affecting X-ray emission:

(i) mA;

(ii) kVp;

(iii) Filtration; and

(iv) Voltage waveform.

(c) Principles of radiation protection:

(A) Collimation;

(B) Types of personal protection equipment and who must wear it;

(C) ALARA;

(D) Time, distance, shielding;

(E) Operator safety;

(F) Personal dosimetry:

(i) Types of dosimetry;

(ii) Proper placement of dosimetry; and

(iii) Situations that require dosimetry.

(G) Occupational and non-occupational dose limits.

(d) Radiographic technique:

(A) Factors affecting technique choice:

(i) Thickness of part;

(ii) Body composition;

(iii) Pathology; and

(iv) Film versus computed radiography (CR) and digital radiography (DR).

(B) How to develop an accurate chart;

(C) Low dose techniques;

(D) Pediatric techniques (does not apply to veterinary); and

(E) AEC Techniques.

(e) Darkroom:

(A) Safelights;

(B) Chemical storage;

(C) Film storage; and

(D) Darkroom cleanliness.

(f) Image processing:

(A) Automatic film processing;

(B) Dip tank film processing;

(C) Computed radiography (CR) processing; and

(D) Digital radiography (DR) processing.

(g) Image critique:

(A) Reading room conditions;

(B) Light box conditions;

(C) Image identification;

(D) Artifacts;

(E) Exposure indicators for CR and DR;

(F) Technical parameter evaluation; and

(G) Positioning evaluation.

(h) Veterinary X-ray use (for veterinary courses only):

(A) Types of animal restraints;

(B) Small animal versus large animal;

(C) Film holders; and

(D) Portable X-ray machine safety.

(i) Applicable federal and state radiation regulations including those portions of chapter 333, divisions 100, 101, 103, 106, 111, 120, and 124.

(24) Dental X-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:

(a) Currently licensed by the Oregon Board of Dentistry as a Dentist or Dental Hygienist;
or

(b) Is a Dental Assistant who is certified by the Oregon Board of Dentistry in radiologic proficiency; ~~and~~

~~(c) Successfully completed didactic and clinical radiography training covering the subject areas outlined in section (1) of this rule; and~~

~~(d) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered by the Dental Assisting National Board, Inc. (DANB) and clinical radiography examination or other comparable requirements approved by the Oregon Board of Dentistry.~~

(c) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the direct supervision of a Dentist or Dental Hygienist currently licensed, or a Dental Assistant who has been certified in radiologic proficiency by the Oregon Board of Dentistry.

~~(3) Medical X-ray equipment operators not regulated by the Oregon Board of Medical Imaging. In addition to the above, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of X-ray examinations that the individual will be performing; and~~

~~(a) Have 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer; and~~

~~(b) Must have completed the required radiation use and safety hours and a minimum of 50 hours in X-ray laboratory before X-raying a human patient.~~

~~(4) Radiation Use and Safety Instructor Qualifications. The training required in sections (1), (2) and (3) of this rule must be taught by an Authority approved instructor. Approval will be based upon the following criteria:~~

~~(a) Medical use and safety instructor: An individual who is currently licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging;~~

~~(b) A dental radiation use and safety instructor is an individual who has:~~

~~(A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered DANB; or~~

~~(B) Has been evaluated and approved as a qualified Dental radiation use and safety instructor by the Oregon Board of Dentistry; and~~

~~(C) Is currently licensed by the Oregon Board of Dentistry as a dentist; or~~

~~(D) Is a dental hygienist; or~~

~~(E) Is a dental assistant certified in Radiologic proficiency and has a minimum of two years of experience in taking dental radiographs.~~

~~(c) A veterinarian radiation use and safety instructor is an individual who is:~~

~~(A) Currently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a Radiologic Technologist by the Oregon Board of Medical Imaging; and~~

~~(B) Has completed training specific to veterinarian radiography, including training in animal restraint; and~~

~~(C) Have a minimum of two years of experience in taking veterinary radiographs.~~

~~(d)(A) On a case by case basis, if an evaluation by the Authority reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in subsections (4)(a), (4)(b) or (4)(c) of this rule or is an individual who is qualified under OAR 333-101-0230 as a Hospital Radiology Inspector; or~~

~~(B) The individual meets the requirements of a qualified expert as defined in OAR 333-100-0005(80).~~

~~(5) In addition to the requirements in sections (2), (9), (10) and (13), of this rule dental X-ray equipment operator must also satisfy any requirements established by the Oregon Board of Dentistry.~~

~~(6) The operator shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.~~

~~(7) Any diagnostic medical X-ray operators who meet the following requirements are considered to have met the requirements of section (1) of this rule: is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:~~

(a) Holds a current license from the Oregon Board of Medical Imaging; or

(b) Holds a current limited X-ray machine operator permit from the Oregon Board of Medical Imaging; or

(c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the direct supervision of a radiologist who is currently licensed with the Oregon Medical Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Medical Imaging; or

(d) Is a student in an Oregon Board of Medical Imaging approved limited permit program under a Radiologic Technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Medical Imaging.

(6) In addition to the training outlined in section (3) of this rule, medical X-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Medical Imaging, must have 100 hours or more of instruction in radiologic technology including, but not limited to:

(a) Anatomy physiology, patient positioning, exposure and technique; and

(b) Appropriate types of X-ray examinations that the individual will be performing; and in addition

(c) Receive 200 hours or more of X-ray laboratory instruction and practice in the actual use of an energized X-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer.

~~(8) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect supervision of a Dentist or Dental Hygienist currently licensed or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry provided that:~~

~~(a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or~~

~~(b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and~~

~~(c) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (1) of this rule; and~~

~~(d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through:~~

~~(A) The use of mannequins under indirect supervision; or~~

~~(B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and~~

~~(C) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site(s) of their clinical training and available for review by the Oregon Health Authority, Public Health Division inspection staff at the time of inspection.~~

~~(9) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 of these rules.~~

~~(10) The students identified in section (8) of this rule are considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of 12 consecutive months.~~

(7) All X-ray operators shall be able to demonstrate competency in the safe use of the X-ray equipment and associated X-ray procedures.

(8) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.

(a) Records of this training must be maintained and made available to the Authority for inspection.

(b) The training may be in any format such as hands-on training by a manufacturer's representative, video or DVD instruction, or a training manual.

~~(11) Radiation use and safety training programs approved prior to the May 1, 2005 will continue to be considered as meeting the requirements of section (1) of this rule provided they cover those portions of the Oregon Rules for the Control of Radiation indicated in subsection (1)(h) of this rule.~~

~~(12) X-ray operator training approved prior to May 1, 2005 will continue to be considered as having met the requirements of sections (1), (2) or (3) of this rule as applicable.~~

~~(13)~~ **Reciprocity.** X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements **listed** in sections (1) ~~or (2)~~ of this rule, if the Authority's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of sections ~~(1) or (2)~~ **(3)** of this rule.

~~(14) When required by the Authority, applications training must be provided to the operator before use of X-ray equipment on patients.~~

~~(a) Records of this training must be maintained by the registrant for inspection.~~

~~(b) The training may be in any format such as hands on training by a manufacturer's representative, video or DVD instruction, or a training manual.~~

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0060

Radiation Use and Safety Instructor Qualifications

The training required in OAR 333-106-0055(1) must be taught by an Authority approved instructor. Approval will be based upon the following criteria.

(1) A medical use and safety instructor is an individual who is currently:

(a) Licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Medical Imaging; or

(b) A dental radiation use and safety instructor is an individual who is currently licensed by the Oregon Board of Dentistry as a Dentist, a Hygienist, or has been approved by the Oregon Board of Dentistry as a radiation use and safety instructor.

Stat. Auth.: ORS 453.605 – 453.807

Stats. Implemented: ORS 453.605 – 453.807

Fluoroscopic X-ray Systems Requirements

333-106-0201

Fluoroscopic X-ray Systems

All fluoroscopic X-ray systems shall meet the following requirements:

~~Limitations of Useful Beam~~

(1) Primary Barrier:

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID;

(b) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Nonimage intensified types of fluoroscopes shall not be used.

(3) Image-Intensified Fluoroscopy and Spot Filming:

(a) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. In addition:

(A) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID ~~and~~ or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the X-ray field;

(B) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 cm by 5 cm or less;

(C) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and

(D) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(b) Spot-film devices which are certified components shall meet the following additional requirements:

(A) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

(B) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 cm by 5 cm;

(C) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

(D) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(c) If a means exists to override any of the automatic X-ray field size adjustments required in section (23) of this rule, that means:

(A) Shall be designed for use only in the event of system failure;

(B) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

(C) Shall be clearly and durably labeled as follows:

"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"

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:

(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;

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

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

(e) 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.

(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: 453.605 - 453.807

333-106-0210

Fluoroscopic Entrance Exposure Rates

(1) Fluoroscopic equipment manufactured before May 19, 1995 that is provided with Automatic Exposure Rate Control (AERC) shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (R) (2.58 mC/kg) per minute, at a point where the center of the useful beam enters the patient, except:;

(a) During the recording of fluoroscopic images; or;

(b) When optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment that is provided with both an AERC and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute in either mode at a point where the center of the useful beam enters the patient, except:

(a) During the recording of fluoroscopic images; or

(b) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in sections (1), (2), and (3) of this rule.

(5) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements will apply:

(a) Fluoroscopic equipment operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where

the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of the technique factors may be provided.

(b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute at a point where the center of the useful beam enters the patient except:

(A) During the recording of fluoroscopic images from an X-ray image-intensifier tube using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(B) When an optional high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 R per minute at a point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(6) Measuring compliance. Compliance with the requirements of this rule shall be determined as follows:

(a) Movable grids and compression devices shall be removed from the useful beam during the measurement;

(b) If the source is below the table, exposure rate shall be measured 1 cm above the tabletop or cradle;

(c) If the source is above the table, the exposure rate shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

(d) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly;

(e) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is moveable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the X-ray table.

(7) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirement set forth in section (5) of this rule.

(8) Periodic measurement of entrance exposure rate shall be performed as follows:

(a) Such measurement shall be made annually or after any maintenance of the system which might affect the exposure rate; and

(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in OAR 333-106-0105(1)(c) ~~of these rules~~. The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results; and

(c) Personnel monitoring devices may be used to perform the measurements required by subsection (8)(a) of this rule, provided the measurements are made as described in subsection (8)(d) of this rule;

(d) Conditions of periodic measurement of entrance exposure rate are as follows:

(A) The measurement shall be made under the conditions that satisfy the requirements of section (6) of this rule; and

(B) The kVp shall be the kVp typical of clinical use of the X-ray system; and

(C) The X-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system or the worst case; and

(D) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the X-ray system.

NOTE: Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0215

Fluoroscopic Barrier Transmitted Radiation Rate Limits

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two mR (0.516 uC/kg) per hour at 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring Compliance of Barrier Transmission:

(a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm;

(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop;

(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm;

(d) Movable grids and compression devices shall be removed from the useful beam during the measurement; and

(e) The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0220

Fluoroscopic Indication of Potential and Current

During fluoroscopy and cinefluorography ~~X~~-ray tube potential and current shall be continuously indicated. Deviation of ~~X~~-ray tube potential and current from the indicated values shall not exceed the maximum deviation stated by the manufacturer.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.625, 453.635 & 453.695

333-106-0225

Fluoroscopic Source-to-Skin Distance

The source-to-skin distance shall not be less than:

(1) ~~Thirty-eight~~38 centimeters on stationary fluoroscopes manufactured on or after August 1, 1974;

(2) 35.5 cm on stationary fluoroscopes manufactured prior to August 1, 1974;

(3) 30 cm on all mobile fluoroscopes; and

(4) 20 cm for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0240

Fluoroscopic Control of Scattered Radiation

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall not be less than 0.25 mm lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(a) Is at least 120 cm from the center of the useful beam; or

(b) The radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, Bucky-slot cover, sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in OAR 333-106-0025 ~~of these rules~~;

(c) Upon application to the Authority, providing adequate justification, exceptions to this section may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0245

Fluoroscopic Radiation Therapy Simulation Systems

Radiation therapy simulation systems shall be exempt from all the requirements of OAR 333-106-0201 through 333-106-0245 ~~of these rules~~ provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the ~~X~~-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of OAR 333-106-0230 ~~of these rules~~ are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Additional Requirements for Radiographic Machines

333-106-0301

Beam Limitation for Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography(CT) X-ray Systems Beam Limitation

(1) The useful beam shall be limited to the area of clinical interest.

(2) General Purpose Stationary and Mobile X-ray Systems:

(a) There shall be provided a means for stepless adjustment of the size of the X-ray field, where the adjustment of each dimension of the field is independent of the other;

(b) A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam;

(c) Evidence of compliance with subsections (2)(a) and (b) of this rule shall be shown on each radiograph taken, either by imaging part of the collimator on the radiograph or by imaging collimator nubs or pointers;

(d) Beam-defining lights used for visually defining perimeters of the X-ray field shall have an illumination great enough to be visualized by the operator under ambient light conditions;

(e) The Authority may grant an exemption on noncertified X-ray systems to subsections (2)(a) and (b) of this rule provided the registrant makes a written application for such exemption and in that application:

(A) Demonstrates it is impractical to comply with subsections (2)(a) and (b) of this rule; and

(B) The purpose of subsections (2)(a) and (b) of this rule will be met by other methods.

(3) ~~Additional Requirements for Stationary General Purpose X-ray Systems.~~ In addition to the requirements of section (2) of this rule, all stationary general purpose X-ray systems shall meet the following requirements:

(a) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

(c) Indication of field size dimensions and SID's shall be specified in inches ~~and/or~~ centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(4) ~~X-ray Systems Designed for One Image Receptor Size.~~ Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(5) Special Purpose X-ray Systems:

(a) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

(b) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor;

(c) Subsections (5)(a) and (b) of this rule may be met with a system that meets the requirements for a general purpose X-ray system as specified in section (2) of this rule or, when alignment means are also provided, may be met with either:

(A) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(B) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0325

Intraoral Dental Radiographic Systems

~~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(~~7789~~), 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}): $E \geq 5(E_{max} - E_{min})$

(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 ~~subsection (2)(a)~~ of this rule or its updated version;

(d) All patients shall be provided with a leaded apron during any dental X-ray exposure;

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

(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Authority.

(8) Hand-held X-ray systems.

(a) Registrants must provide for security and safe storage while not in use. A report must be filed with the Authority within 72 hours if the hand-held unit is lost or stolen.

(b) The image receptor used with hand-held dental X-ray systems must either be:

(A) A speed class of intra-oral film designated as "E/F", "F" or faster; or

(B) A digitally acquired image (CR or DR).

(c) The hand-held X-ray system must be equipped with a permanently attached backscatter shield of 0.25 mm Pb equivalent.

(d) The backscatter shield must be designed to appropriately protect the operator during an exposure. The manufacturer of the hand-held unit must provide documentation to the Authority of the design specifications of the backscatter shield's protection to the operator prior to sale and distribution in the State of Oregon.

(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(3).

(A) The hand-held unit shall not be used for patient examinations in hallways and waiting rooms.

(B) The unit can only be operated in an enclosed room when possible. All individuals except the X-ray operator and the patient must leave the room and stand behind a protective barrier or be at least six feet from the X-ray source if a protective barrier is not available during radiographic exposures.

(c) Operators must complete machine specific applications training as described in OAR 333-106-0055(~~148~~) before using a hand-held unit.

(A) Training on the safe use of the unit shall be documented and include at a minimum:

(i) Proper positioning of the unit to ensure an adequate protected position;

(ii) Limitations on the use of position indicating devices that require longer distances to the patient's face;

- (iii) Diagrams such as drawings, illustrations, or schematics of protected position and location in relationship to the unit;
 - (iv) Diagrams such as drawings, illustrations, or schematics of the effect of improper distance or removal of shielding device; and
 - (v) 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

Veterinary X-ray Systems

333-106-0601

Veterinary Medicine Radiographic Installations Additional Requirements

(1) Equipment:

- (a) The protective tube housing shall be of the diagnostic type;
- (b) Collimating devices shall be provided and used for collimating the useful beam to the area of clinical interest;
- (c) All X-ray equipment sold (~~etc.~~) after October 1991 must be equipped with a variable adjustable collimator and beam-defining light that meets all of the requirements of OAR 333-106-0301(1), (2) and (3) ~~of these rules~~;
- (d) The total filtration permanently in the useful beam shall not be less than 0.5 mm Al equivalent for machines operating up to 50 kVp, 1.5 mm Al equivalent for machines operating between 50 and 70 kVp, and 2.5 mm Al equivalent for machines operating above 70 kVp;
- (e) A device shall be provided to terminate the exposure after a preset time or exposure;

(f) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 12 feet (3.66 m) from the animal during all X-ray exposures.

(2) Structural Shielding: All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with division 120.

(3) Operating Procedures:

(a) All individuals shall stand well away from the useful beam and the animal during radiographic exposures;

(b) No individual shall be in the X-ray room while exposures are being made unless such individual's assistance is required;

(c) When an animal must be held in position during radiography, mechanical supporting or restraining devices shall be available and used as appropriate.

(d) If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and that individual shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored with appropriate personnel monitoring devices.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

Mammography Requirements

333-106-0700

Mammography X-Ray Systems Definitions

In addition to the definitions provided in division 100 and 106 of this chapter, the following definitions shall be applicable to the rules in this division.

(1) "Air Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a given mass of air. The unit used to measure the quantity of kerma is the gray (Gy). For X-rays with energies below 300 kiloelectronvolts (keV), 1Gy=100 rad and is equivalent to 114 (R) of exposure.

(2) "FDA" means the Food and Drug Administration.

(3) An "image receptor support surface" means that portion of the image receptor support which is the X-ray input surface and is used to support the patient's breast during mammography.

(4) "Interpreting physician" means a licensed physician who interprets mammographic images and meets the qualifications of OAR 333-106-0750(2)-of these rules.

(5) "Lead Interpreting Physician" means a physician who interprets mammographic images, meets the qualifications of OAR 333-106-0750(2)-of these rules, and who has the general responsibility for ensuring that the registrant's quality assurance program meets all applicable rules and regulations.

(6) "Mammographic screening" means the use of radiation to test women for the detection of diseases of the breast when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such tests for the purposes of diagnosis. Screening is considered as self-referral by asymptomatic women without physicians orders (see OAR 333-100-0020(5)(6) and 333-106-0035(3)).

(7) "Mammography" means radiography of the breast.

(8) "Mammography equipment evaluation" means an onsite assessment of a mammography unit(s) or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable state and federal standards.

(9) "Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum; An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

(10) "Medical Physicist" means a person trained in evaluating the performance of mammography equipment and quality assurance programs and meets the qualifications of OAR 333-106-0750(3)-of these rules.

(11) "MQSA" means the Mammography Quality Standards Act of 1992.

(12) "Phantom" means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. (The "FDA accepted phantom" meets this requirement.)

(13) "Quality Assurance" is a comprehensive concept that comprises all of the management practices instituted by the registrant or the registrant's representative/s to ensure that:

(a) Every imaging procedure is necessary and appropriate to the clinical problem at hand;

(b) The images generated contain information critical to the solution of that problem;

(c) The recorded information is correctly interpreted and made available in a timely fashion to the patient's physician;

(d) The examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient, consistent with subsection (13)(b) of this rule.

(14) "Quality Assurance Program" includes such facets as efficacy studies, continuing education, quality control, preventive maintenance, and calibration of equipment.

(15) "Quality Control" means a series of distinct technical procedures that ensure the production of a satisfactory product, ~~e.g.,~~ such as a high quality screening or diagnostic image.

(16) "Quality Control Technologist" means an individual who is qualified under MQSA, and who is responsible for those quality assurance responsibilities not assigned to the Lead Interpreting Physician or to the Medical Physicist.

(17) "Resting period" means the period of time necessary to bleed out air that has been trapped between the radiographic film and intensifying screen during the loading process in the darkroom. This period of time is usually measured in minutes and determined by the individual manufacturer of the intensifying screen/mammography cassette combination.

(18) "Standard Breast" means a 4.2 cm thick compressed breast, consisting of 50 percent adipose, and 50 percent glandular tissue.

(19) "Survey" means an onsite physics consultation and evaluation of a registrant's mammography equipment, and quality assurance program performed by a medical physicist.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

333-106-0735

Breast Density Notification

(1) As used in this rule:

(a) "Breast Density" refers to the relative amount of different tissues present in the breast. A dense breast has less fat than glandular and connective tissue. Mammogram films of breasts with higher density are harder to read and interpret than those of less dense breasts. (Source: National Cancer Institute).

(b) "Facility" has the meaning given that term in 42 U.S.C. 263b and includes but is not limited to a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility that conducts breast cancer screening or diagnosis through mammography activities. "Facility" does not include a facility of the Department of Veterans Affairs.

(c) "Mammography activities" means the operation of equipment to produce a mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation.

(2) In all cases where a mammogram shows a patient has extreme or heterogeneous breast density, the facility shall incorporate the following notification within the lay summary mammography report provided to the patient: ~~When a mammogram shows a patient has heterogeneous breast density, the decision of whether or not to incorporate the patient notification is left to the interpreting radiologist's discretion:~~

DENSE BREAST TISSUE NOTIFICATION

Your mammogram shows that your breast tissue is dense. ~~For most women, breast density decreases with age, but in some women, there is little change.~~ Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your find cancer on a mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given provided to you ~~by Oregon State Law~~ to raise your awareness and to promote discussion with your health care provider. ~~about your own risk for breast cancer.~~ Together, you can decide if you may benefit from further screening. if additional breast imaging tests such as a breast ultrasound, Magnetic Resonance Imaging (MRI) or Breast Specific Gamma Imaging (BSGI) would be beneficial based on your risk factors and physical examinations. A report of your results was sent to your health care provider.

(3) The Dense Breast Tissue Notification statement and guidelines shall be included in the facility's policy on how they communicate mammography results to the patient and their health care providers.

Stat. Auth.: ORS 413.042 & 2013 OL Ch. 411
Stats. Implemented: 2013 OL Ch. 411

333-106-0750

Mammography Personnel Qualifications

(1) Operator qualifications. In order to use any mammography X-ray machine the operator of the mammography X-ray unit must have the following qualifications:

(a) Have a current license issued by the Oregon Board of Medical Imaging; and

(b) Have prior to the effective date of these rules qualified as a radiologic technologist under the MQSA interim rules or completed 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging patients with breast implants;

(B) The performance of 25 examinations under the ~~direct~~-personal supervision of an individual qualified under this section; and

(C) At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(D) Be currently registered and in good standing with the American Registry of Radiologic Technologist (ARRT); and

(E) Be certified in mammography by the ARRT or the equivalent; or

(F) Provide documented evidence that an ARRT mammography certification test is scheduled. Technologists meeting the requirements of subsection (1)(a) and paragraphs (1)(b)(A), (B), (C), and (D) of this rule may work under the supervision (supervision means that a fully qualified technologist is on-site and readily available to answer questions or assist) of a technologist, meeting all of the requirements of this rule, for up to one year while waiting to take the certification test.

(2) Interpreting Physician qualifications. All physicians interpreting mammograms shall meet MQSA qualifications and hold a current license to practice medicine in the State of Oregon.

(3) Medical Physicist qualifications. All Medical Physicists conducting surveys and equipment evaluations of mammography facilities and providing oversight of their quality assurance programs shall;

(a) Meet MQSA requirements; and

(b) Be currently licensed as a vendor by the Authority.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 116

USE OF RADIONUCLIDES IN THE HEALING ARTS

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

(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.

(c) 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

333-116-0190

Authorization for Calibration and Reference Source

Any person authorized by OAR 333-116-0030 for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to OAR 333-102-0290 or equivalent provisions of the U.S. Nuclear Regulatory Commission (NRC) Agreement State or Licensing State and that do not exceed 1.11GBq (30 mCi) each;

(2) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life of 100 days or less in individual amounts not to exceed 1.11GBq (30 mCi), except Y-90 sources not to exceed 2.8 GBq (75 mCi);

(3) Any radioactive material listed in OAR 333-116-0300, 333-116-0320 or 333-116-0360 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 uCi) each; and

(4) Technetium-99m in amounts as needed. individual amounts to exceed 1.85 GBq (50 mCi).

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 119

REGISTRATION OF TANNING FACILITIES

333-119-0010

Definitions

(1) "Authority" means the Oregon Health Authority.

(2) "Customer" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.

(3) "Employee" means any individual, including a minor whether lawfully or unlawfully employed, who engages to furnish services for remuneration, financial or otherwise, subject to the direction and control of an employer and includes any individual who is required to have workers' compensation coverage.

(4) "EPA" means the U.S. Environmental Protection Agency.

(5) "FDA" means the U.S. Food and Drug Administration.

(6) "Fitzpatrick Skin Type Scale" means a numerical classification diagram used as a way to classify the response of different types of skin to ultraviolet (UV) light.

(7) "Formal Training" means a course of instruction reviewed and approved by the Authority and which is conducted or presented under formal classroom conditions or online by a qualified expert possessing adequate knowledge and experience to offer a curriculum, associated training, and certification testing pertaining to and associated with the correct use of tanning equipment. Operator training shall cover ultraviolet radiation and effects on the skin, photosensitivity, FDA and State of Oregon regulations, eye protection, and equipment maintenance.

(87) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.

(98) "Identification" means:

(a) A government-issued photo identification that displays the individual's date of birth;
or

(b) A government or non-government issued photo identification when submitted with a completed Oregon Underage Tanning Medical Recommendation form.

(109) "Individual" means any human being.

(110) "Minor" means any individual under the age of 18 years old.

(124) "Operator" means the person who is an employee (defined by the Oregon Occupational Safety and Health Division, OAR 437-003-0011(2)) or contractor of the tanning facility who has received a certificate from an approved formal training course and who is responsible for any of the following:

(a) Determining customer's skin type;

(b) Determining the suitability for use of a tanning device;

(c) Providing information regarding the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;

(d) Assuring that all required forms are understood and properly signed by the customer;

(e) Maintaining required exposure records;

(f) Recognizing and reporting injuries or alleged injuries to the registrant;

(g) Determining the customer's exposure schedule;

(h) Setting timers which control the duration of exposure; ~~and~~

(i) Instructing the customer in the proper use of protective eyewear;

(j) Verifying and documenting age of clients; and

(k) Sanitizing tanning devices.

(132) "Other Compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.

(143) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

(154) "Phototherapy Device" means equipment that emits uUltraviolet radiation used by a health care professional in the treatment of disease or illness.

(165) "~~Program~~" means the Radiation Protection Services section of the Public Health Division.

(176) "Protective Eyewear" means suitable eyewear that protects the eye from uUltraviolet radiation and allows adequate vision.

(187) "~~Public Places~~" means the area where members of the public may assemble and are not directly affected by tanning operations.

(198) "~~Recommendation~~" means a written directive using a form provided by the Authority and signed by a licensed physician.

(2049) "Registrant" means a tanning facility registered with the Authority as required by provisions of this division.

(210) "Registration" means registration with the Authority in accordance with provisions of this division.

(22) "Remote" means a timer that is placed away from the tanning device so it can only be programmed by the tanning-operator.

(234) "Safe Level" means not more than 50 colonies of microorganisms per four square inches of equipment surface.

(242) "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product that provides a sufficient concentration of chemicals, and enough time to reduce the bacterial count, including pathogens, to a safe level. ~~Chemical germicides that are registered with EPA as hospital disinfectants when used at recommended dilutions and directions may be approved for sanitizing of tanning devices.~~

(253) Skin Types:

(a) "~~Type 1~~" means skin burns easily and severely (painful burn); tans little or none and peels.

(b) "~~Type 2~~" means skin burns easily and severely (painful burn); tans minimally or lightly and also peels.

(c) "Type 3" means skin burns moderately and tans about average.

(d) "Type 4" means skin burns minimally, tans easily and above average with each exposure; exhibits immediate pigment darkening reaction.

(e) "Type 5" means skin rarely burns, tans easily and substantial; always exhibits immediate pigment darkening reaction

(26) "Storage" means when a tanning device is not actively being used, as evidenced by the removal of all tanning lamps and lack of connection to a power supply.

(274) "Tanning Device" means any equipment used for tanning of the skin, that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, Ultraviolet Lamp, tanning booth, facial unit, UVA wand, or tanning bed. "Tanning device" also means any accompanying equipment, including, but not limited to, protective eyewear, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.

(285) "Tanning Facility" means any location, place, area, structure, or business that provides persons access to any tanning device.

(296) "Timer" means an electronic device designed specifically to terminate tanning sessions at a preset time interval. ~~provided to terminate the exposure at a preset time interval.~~

(3027) "Ultraviolet Radiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

333-119-0020

Registration

(1) Prior to the operation of any tanning device used by the public for a fee or other compensation, the owner or operator shall file an application with the Authority and pay applicable fee(s) in the amount and in the manner specified in OAR 333-103-0025 to register each tanning device.

(2) If the owner or operator owns or operates more than one such tanning facility, the owner or operator shall file a separate application for each such facility owned or operated.

(3) Registration application shall be made on forms furnished by the Authority.

- (4) A validation certificate or acknowledgement of validation will be issued by the Authority.
- (5) The certificate issued by the Authority shall be effective for one year beginning January 1 through December 31.
- (6) The certificate shall be displayed in a conspicuous open public area of the tanning facility.
- (7) The Authority will provide an identification number that will be affixed by an Authority inspector to each tanning device during the initial or follow-up facility inspection:
- (a) Identification numbers shall not be removed without written permission of the Authority; and
 - (b) Identification numbers shall not be defaced.
- (8) The registrant shall notify the Authority in writing before making any change that would render the information contained in the application for registration or the validation of registration no longer accurate.
- (9) No registration may be transferred from one person to another person, from one tanning facility to another tanning facility, or from one tanning device to another tanning device.
- ~~(10) In the event of a change in ownership, the new owner will be required to apply for a registration of the tanning device within 30 days after taking possession of the property.~~
- ~~(11) Tanning facilities already in existence at the time of the effective date of this rule may continue to operate. Such facility shall be given priority in the inspection process by the Authority. However, should those tanning facilities fail to meet the standards, they may be prohibited from continuing to operate until such time as they have met those standards through evaluation by the Authority's inspectors or through a hearing held by the Authority.~~
- (10~~2~~) Failure to properly register a tanning device is subject to the imposition of a civil penalty per ORS 431.950 and ORS 431.262.
- (11~~3~~) The Authority may require tanning facility registrants to complete and update application forms and information concerning tanning devices.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

General Requirements

333-119-0030

Administrative Responsibilities

(1) The registrant shall be responsible for directing the operation of the tanning facility that has been registered with the Authority. That individual or individual's agent shall assure that the provisions of these rules are met in the operation of tanning devices.

(2) A tanning device which does not meet the provisions of these rules shall not be operated and may be tagged "Out of Service for Non-compliance with OAR 333-119 Requirements" by Authority inspectors. Devices tagged as non-compliant shall not be operated until written authorization is received by the registrant from the Authority.

(3) The registrant shall assure that the tanning facility will comply with all applicable federal laws and regulations.

(4) In addition to the requirements of this division, all registrants are subject to the applicable requirements of divisions 100, 103 and 111 of this chapter.

(5) The Authority Inspection Findings report ~~and facility response letter(s)~~ shall be conspicuously posted in public view until all items of non-compliance have been corrected and a written Authority release from this requirement is received by the registrant.

(6) The registrant shall post in a conspicuous place the Authority "Notice To The Public".

(7) The registrant shall ensure that the "Warning", "Notice to the Public" and "Persons Under Age 18" signs are not covered or obscured, and are easily seen by clients at either the main reception area of the establishment or in each tanning device room.

(8) The registrant shall notify the Authority of any injury for which medical attention was sought or obtained from the use of a registered tanning device within one working day after learning of the occurrence, and provide the Authority any information about the incident the Authority deems necessary.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930 & 431.935

333-119-0040

Construction and Operation of Tanning Facilities

Unless otherwise ordered or approved by the Authority, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

(1) All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. Such toilet facilities shall include a ~~water closet~~toilet and hand washing sinks. Such toilet and dressing rooms shall be properly maintained, as well as meet all state and local codes.

~~(2) All areas of the tanning facility shall be ventilated with at least six air changes per hour or as required by local code.~~

~~(23) Rooms or other enclosures containing tanning devices~~ Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during ~~booth~~ operation.

~~(4) The tanning device shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).~~

~~(35) Except as otherwise noted by the Authority, each tanning~~ Tanning facility facilities shall be constructed, operated and maintained in accordance with applicable city, county and state codes.

~~(46)~~ Clean sanitary towels shall be provided to all patrons using tanning facilities.

~~(57)~~ A hamper or receptacle must be provided for all soiled towels and linen.

~~(68)~~ No pets or animals are permitted in tanning facilities other than service animals.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

333-119-0041

Cleaning and Sanitation

(1) All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner by the facility operator.

(2) The tanning device(s) and protective eyewear shall be ~~cleaned~~sanitized after each client use, by the facility operator.

(3) A clean paper or cloth towel shall be used each time the tanning device is ~~cleaned and~~ sanitized.

~~(4) The sanitizer must be specifically manufactured for sanitizing ultraviolet light emitting equipment and protective eyewear, and must not damage the acrylic lamp covers of the device. The ultraviolet light produced by the tanning device itself is not considered an adequate sanitizing agent.~~

(45) An operator cannot require the consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer.

(56) The sanitizer must contain a concentration of Quaternary Ammonium between 400ppm-800ppm.

(6) A test kit that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and tested weekly thereafter to ensure sufficient strength remains within the sanitizing solution.

~~(7) A written policy for cleaning and sanitizing shall be available for employees and the consumer. Written policies need to address the following:~~

~~(a) Tanning device manufacturer's recommended sanitizer solution and cleaning guidelines. If the manufacturer does not recommend a specific sanitizer then the written policy shall contain the name of the sanitizer that is being used on the tanning device and eyewear.~~

~~(b) Materials Safety Data Sheets referring to the sanitizing agent used by the operator.~~

~~(c) Location of the sanitizer and the application instructions.~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

Specific Requirements

333-119-0050

Warning Statement

(1) At each customer's initial visit to a tanning facility, and at least annually thereafter, the customer shall be provided ~~at the following~~ written statement to review and sign, which warns the customer that ~~(a Authority approved tanning client card may be used to satisfy this requirement):~~

~~(a1)~~ Not wearing ~~the appropriate~~ protective eyewear ~~provided to each customer by the tanning facility~~ may cause damage to the eyes; and

~~(b2)~~ Overexposure to the tanning process may cause burns; and

~~(c3)~~ Repeated exposure to the tanning process may cause skin cancer or premature aging of the skin or both; and

~~(d4)~~ Abnormal skin sensitivity or burning may result from the tanning process if the customer is also consuming or using certain foods, cosmetics or medications (such as tranquilizers, antibiotics, diuretics, blood pressure medication or birth control pills); and:

~~(a) Foods;~~

~~(b) Cosmetics; or~~

~~(c) Medications such as tranquilizers, antibiotics, diuretics, high blood pressure medication, antineoplastics or birth control pills; and~~

~~(e5)~~ Any person taking a prescription or over-the-counter drug should consult a physician before using a tanning device; ~~and:~~

(f) The frequency and duration of tanning sessions must not exceed tanning device manufacturer recommendations; and

(g) Frequent users should be regularly screened for skin cancer by a physician.

(2) An Authority approved tanning client card may be used to satisfy the requirement of section (1) of this rule.

(3) The warning language in the written statement must be in 14 point or larger font.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

333-119-0060

Warning Sign

(1) The registrant shall conspicuously post the warning sign described in section (2) of this rule within one meter (39.37 inches) of each tanning device and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the customer before operating the tanning device.

(2) The warning sign in section (1) of this rule shall meet the following requirements:

(a) The sign shall be printed on paper or similar material no smaller than 8.5 inches by 11 inches. Signs are available for printing on the Authority's website.

(b) The major sign heading shall be labeled **"DANGER"** and the section entitled **"FAILURE"** shall be a minimum of Times New Roman, bold with a minimum font size of 40.

(c) The body text shall be a minimum of Times New Roman with a minimum font size of 20.

DANGER -- ULTRAVIOLET RADIATION

Follow instructions.

Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.

Frequent users should be regularly screened for skin cancer.

FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the Ultraviolet radiation. Consult a physician before using sunlamp or tanning device if you are using medications or have a history of skin problems or believe yourself to be especially sensitive to sunlight.

If you do not tan in the sun, you are unlikely to tan from the use of this product

Tanning session frequency and time shall not exceed the device manufacturer's recommendations

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

333-119-0070

Protective Eyewear

(1) The registrant shall ~~provide~~ make available protective eyewear ~~to each customer~~ for use during ~~any use of~~ tanning sessions~~devices~~.

(2) The protective eyewear in section (1) of this rule shall meet the requirements of 21 Code of Federal Regulations (CFR) Part 1040, Section 1040.20(c)(4).

(3) Tanning facility operators shall ensure, before each tanning session, that clients have approved protective eyewear ~~that customers wear the protective eyewear required by this rule.~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

333-119-0080

Training of Personnel

~~(1) The registrant shall maintain documentation to verify that all tanning device operators are adequately trained in the following:~~

~~(a) The rules of this division;~~

~~(b) Procedures for correct operation of the tanning facility and tanning devices;~~

~~(c) Recognition of injury or overexposure to Ultraviolet radiation;~~

~~(d) The tanning device manufacturer's procedures for operation and maintenance of the tanning devices;~~

~~(e) The determination of skin type of customers and appropriate determination of duration of exposure to registered tanning devices;~~

~~(f) Emergency procedures to be followed in case of injury; and~~

~~(g) Potential photosensitizing foods, cosmetics, and medications.~~

~~(12)~~ The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.

~~(23)~~ All operators of registered tanning devices must successfully complete an Authority approved tanning training course ~~in the State of Oregon~~ prior to commencement of tanning operations.

(3) Approved training will include, at a minimum, content covering the rules of this division, skin typing, recognition of overexposure, as well as any other topic determined by the Authority to be critical to client protection.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

333-119-0090

Protection of Consumers

The registrant and operators are responsible for protecting the customers from overexposure to Ultraviolet Light by ensuring that:~~shall establish and use a procedure manual that will aid in the protection of the customer to excessive or unnecessary exposure to Ultraviolet Light. This manual shall include, but not be limited to, the following instructions:~~

- (1) Only one customer may occupy the tanning room. In the case of a customer using a tanning device who may need the aid or assistance from another person, that individual must also be provided with and wear protective eyewear.
- (2) No customer under the age of 18 years shall be allowed to use a tanning device without a completed Oregon Underage Tanning Medical Recommendation form completed by a licensed physician and identification. The recommendation:
 - (a) Must identify the physician and client and describe the recommended tanning session frequency(s) and duration(s);
 - (b) Must identify dates for starting and ending of the tanning sessions; and
 - (c) Cannot exceed the exposure scheduled per OAR 333-119-0100(14)(b).
- (3) A sign shall be posted in conspicuous view at or near the reception area with the following text in a minimum of at least 36 point type:

"PERSONS UNDER AGE 18 ARE NOT ALLOWED TO USE A TANNING DEVICE WITHOUT A WRITTEN RECOMMENDATION FROM A LICENSED PHYSICIAN"¹²²
- (4) Each person using a tanning device shall be instructed by the operator on the maximum exposure time and proper exposure distance, as recommended by the manufacturer of the device. The operator shall also instruct the customer as to the location and proper operation of the tanning device's emergency shut off switch.
- (5) Infants and minors are not permitted to be in the tanning device room during exposure by parents or guardians.
- (6) Tanning operators shall limit exposure time to ~~the exposure time recommendation provided by the the~~ device manufacturer's recommendations on the tanning device or in the device operating manual. The maximum exposure time recommended by the manufacturer of the device shall not be exceeded in any 24-hour period.
- (7) A copy of the manufacturer's recommended exposure schedule shall be maintained at the remote timer controls for each device.

(8) At the time of their initial visit, all clients shall have their skin type determined according to the Fitzpatrick Skin Type Scale, and their skin type recorded in the client record.

~~(7) Tanning facilities shall post the following signs visible to the customer:~~

~~(a) "In Case Of An Emergency, Dial 911";~~

~~(b) "Oregon Radiation Protection Services at (971) 673-0490".~~

(89) Tanning operators shall maintain a list of the common photosensitizing agents as provided by the Public Health Division, FDA, or other appropriate authorities, available for review by customers.

(910) Tanning facilities are prohibited from controlling the use of tanning devices solely with token timer systems or a mechanical timer system.

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

333-119-0100

Equipment

(1) The registrant shall use only tanning devices manufactured in accordance with the specifications set forth in 21 CFR Part 1040, Section 1040.20, "Sunlamp Products and Ultraviolet Lamps Intended for Use in Sunlamp Products."

~~(2) Each sunlamp product or Ultraviolet Lamp used in these facilities shall not emit measurable Ultraviolet C radiation.~~

~~(3) Each Ultraviolet Lamp contained within the sunlamp product shall be shielded so as to not come into contact with the customer. A transparent acrylic cover shall be used for this purpose.~~

~~(4) Tanning booths in which the customer is in a standing position shall be provided with a handrail for the customer to hold onto during operation of the booth.~~

~~(a) The construction of the booth shall be such that it will have the strength to withstand the stress of use and the impact of a falling person.~~

~~(b) Entry to stand-up booths shall be of rigid construction with doors which are non-latching and open outwardly.~~

~~(5) Each tanning device shall have, clearly marked, the appropriate position the customer is to assume prior to operation.~~

~~(26) Each tanning device shall be labeled in accordance with 21 CFR Part 1040. prominently display the following label or equivalent warning/information label:~~

~~DANGER—ULTRAVIOLET RADIATION.~~

~~FOLLOW INSTRUCTIONS CAREFULLY~~

~~DO NOT ENTER WITHOUT PROTECTIVE EYEWEAR~~

~~(37) Adequate means shall be provided to enable a customer to summon assistance from the exposure position.~~

~~(48) All persons hired for servicing and repair of tanning devices shall be an Authority licensed service technician or State of Oregon licensed electricians.~~

~~(59) Original Equipment Manufacturer (OEM) replacement parts (or equivalent) shall be used, if available, to prevent UL/ETL delisting of tanning devices. All local, State of Oregon, and National Electrical electrical Codes codes must be observed during service and repair actions.~~

~~(640) Replacement lamps shall be certified by the manufacturer as equivalent to Defective or burned out tanning lamps or bulbs shall be replaced with a type intended for use in the device and shall be of the same Ultraviolet range (A or B) as the manufacturer specifies, and shall be the original lamp type as specified by the manufacturer, or certified as an equivalent lamp per 21 CFR 1040.20.~~

~~(744) If equivalent lamps are used instead of the Original Equipment Manufacturer (OEM) required lamps, a copy of the equivalency certification, provided by the lamp supplier, shall be maintained on file for review by the Authority during inspections. inspectors.~~

~~(842) Lamps removed from a tanning device Defective or burned out tanning lamps and tanning lamps which have been operated in a tanning device for the manufacturer's maximum rated lamp hour life, shall be disposed of in a safe and proper manner to prevent unauthorized and unsafe use as lighting devices. Used tanning lamps are prohibited from being resold for any purpose.~~

~~(439) If the uUltraviolet tanning device is not in an individual cubicle, then a suitable screen, curtain, or other shield shall be provided, maintained, and used to prevent unnecessary exposure to uUltraviolet radiation of persons not using the device.~~

~~(14) The facility operator shall ensure that customers do not exceed the exposure time indicated by the manufacturer.~~

~~(1510)~~ Each tanning device shall have a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20 (c)(2).

~~(a11)~~ The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time, or 20 minutes, whichever is less.

~~(12b)~~ A tanning facility shall use the following exposure schedule ~~or an equivalent schedule to accommodate for~~ tanning devices originally designed with a 30 minute maximum exposure timers that ~~are~~ have been reduced to a 20 minute maximum exposure timers.: A copy of this exposure schedule must be affixed to the tanning device, and a copy maintained at the timer controls.

~~(aA)~~ Skin type 1:

~~(Ai)~~ Week 1: 1-3 minutes;

~~(Bii)~~ Week 2: 4-6 minutes;

~~(Ciii)~~ Week 3: 7-10 minutes;

~~(Div)~~ Week 4: 11-15 minutes.

~~(bB)~~ Skin type 2 and 3:

~~(Ai)~~ Week 1: 4 minutes;

~~(Bii)~~ Week 2: 8 minutes;

~~(Ciii)~~ Week 3: 12 minutes;

~~(Div)~~ Week 4: 16 minutes;

~~(Ev)~~ Weekly maintenance: 20 minutes.

~~(cC)~~ Skin Type 4 and 5:

~~(Ai)~~ Week 1: 4 minutes;

~~(Bii)~~ Week 2: 12 minutes;

~~(Ciii)~~ Week 3: 16 minutes;

~~(Div)~~ Week 4: 20 minutes;

~~(Ev)~~ Weekly maintenance: 20 minutes.

(13e) Tanning device timers shall be controlled by a ~~properly~~ trained operator. A remote timer control system shall be used for this purpose.

~~(14)~~ Each tanning device shall be equipped with a functional emergency shut-off mechanism to allow manual termination of the UV exposure by the customer, as required by 21 CFR 1040.20(c)(3).

~~(15)~~ Each timer must be functional and accurate to within ± 10 percent.

~~(16)~~ The registrant shall ensure that the timer is checked annually for accuracy and the results recorded.

(17) The registrant shall ensure that the emergency shut-off is tested annually for proper function and results recorded.

(18) All tanning devices shall be maintained to the minimum requirements of the manufacturer.

~~(19) Each tanning device shall be equipped with an hour meter to accurately determine lamp hour use and recording of maintenance service on each device.~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.655, 431.930 & 431.945

333-119-0110

Records and Reports

(1) The registrant shall maintain a record of each customer's total number of tanning visits, dates and durations of tanning exposures.

(2) The registrants shall maintain a record of each customer's signature and acknowledgement that they understand the potential risks involved with exposure to uUltraviolet radiation and overexposure, and that they have reviewed a photosensitizing drug list.

(3) The registrant shall maintain and have available when requested by the Authority, all completed Oregon Underage Tanning Medical Recommendation forms with copies of the identification used for each minor allowed to use a tanning device.

(4) Upon their initial visit, all tanning clients must present acceptable identification as proof of age. Any tanning client who appears to be under the age of 26 years shall be required to show identification. The type of identification, identification number, client's name, and date of birth shall be recorded by the registrant in the client's record. When requested by the Authority, records shall be available for review.

~~(5) The registrant shall submit to the Authority a written report of injury for which medical attention was sought or obtained from the use of registered tanning devices within five working days after occurrence. The report shall include:~~

~~(a) The name, address and phone number of the affected individual;~~

~~(b) The name, location and phone number of the tanning facility involved;~~

~~(c) The nature of the actual or alleged injury; and~~

~~(d) Any other information relevant to the actual or alleged injury to include the date and duration of exposure and any documentation of medical attention sought or obtained.~~

~~(6) The registrant shall maintain records showing the results of annual timer tests.~~

~~(57) The registrant shall maintain a record of operator training as required in OAR 333-119-0080(43).~~

~~(68) The registrant shall maintain a copy of the owner's manual for each tanning device. the following information for each tanning device:~~

~~(a) Manufacturer's equipment manual and any other service related material or instruction; and~~

~~(b) The exposure schedule developed by the manufacturer; and~~

~~(c) Records of surveys, inspections, maintenance, and modifications performed on the tanning device with names of persons performing such services, the date of service, and the hour meter reading of the device serviced.~~

~~(79) Records shall be maintained showing the receipt, transfer, repair and method of disposal of all tanning devices and lamps.~~

~~(840) All required records shall be maintained in a location and format until inspected by the Authority and shall be so filed as to be readily available for review during inspections conducted by the Authority.~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

333-119-0120

Advertising

(1) Registrants shall not claim or distribute promotional materials that claim using a tanning device is safe, free from risk or that using the device will result in medical or health benefits. Only cosmetic claims can be promoted.

(2) No person, in any advertisement, shall refer to the fact that such person, or such person's facility is registered with the Authority pursuant to the provisions of this division, and no person shall state or imply that any activity under such registration has been approved by the Authority.

~~(3) No person or facility shall advertise or promote tanning packages labeled as "unlimited".~~

~~(4) Tanning packages shall include the following written tanning guidelines for all clients:~~

~~(a) Initial tanning sessions (three to five) are limited to intervals of at least 48 hours between sessions to allow adequate time for melanin activation and transit to occur prior to subsequent exposures. The manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device shall be followed by tanning operators advising new clients during initial tanning sessions.~~

~~(b) After the initial (three to five) tanning exposures, tanning sessions are limited to one tanning session per 24 hour period (or one tanning session per 48 hours on tanning devices so labeled) with customers being properly advised of the manufacturer's recommended exposure schedule posted on tanning devices or listed in the operating manual for the tanning device.~~

~~(c) Promotion of annual tanning packages shall include a written statement listing the total number of sessions allowed per person, per year (recommendations should generally not exceed two sessions per week and the maximum of 30-50 sessions per year as recommended by the International Radiation Protection Association (IRPA) and other authorities).~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.930

333-119-0130

Exemptions

(1) The Authority may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of the rules in this section as it determines are authorized by law and will not result in undue hazard to public health and safety.

(2) A phototherapy device used by or under the direct supervision of a physician licensed under ORS chapter 677 is exempt from the requirements of this division.

(3) Any individual is exempt from the provisions of this division to the extent that such individual owns a tanning device exclusively for personal use.

(4) Tanning devices, while in transit or storage ~~incidental thereto~~, are exempt from the registration provisions of this division.

~~(5) Tanning devices located in any facility having public access are required to have the power supply physically disconnected from the device and lamps removed in order to qualify for a no fee required storage designation. Tanning devices with lamps installed and power active to the device are required to be registered with the Authority and pay applicable fees.~~

Stat. Auth.: ORS 431.925 - 431.955

Stats. Implemented: ORS 431.925 - 431.955

DIVISION 120

STANDARDS FOR PROTECTION AGAINST RADIATION

Surveys and Monitoring

333-120-0200

General

(1) Each licensee or registrant must make or cause to be made, surveys that:

(a) Are necessary for the licensee or registrant to comply with the rules in this division; and

(b) Are reasonable under the circumstances to evaluate:

(A) The magnitude and extent of radiation levels; and

(B) The concentrations or quantities of radioactive material; and

(C) The potential radiological hazards that could be present.

(2) Notwithstanding OAR 333-120-0620, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with

records important for decommissioning. Records must be retained in accordance with 10 CFR parts 30.35(g), 40.36(f), and 70.25

(32) The licensee or registrant must ensure that instruments and equipment used for quantitative radiation measurements (~~such as~~-g. dose rate and effluent monitoring) are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable division or a license condition.

(43) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with OAR 333-120-0100, with other applicable provisions of this division or with conditions specified in a license must be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(54) The licensee or registrant must ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

333-120-0670

Records of Waste Disposal

(1) Each licensee ~~shall~~**must** maintain records of the disposal of licensed materials made under ~~divisions~~ OAR 333-120-0510, 333-120-0520, 333-120-0530, 333-120-0540, 10 CFR Part 61, and disposal by burial in soil, including burials authorized before January 28, 1981.

(2) The licensee ~~must~~**shall retain**~~maintain~~ the records required by section (1) of this rule until the Authority terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination are located in OAR 333-100-0055, 333-102-0355 and 10 CFR Part 72.80 for licensed activities.

Stat. Auth.: ORS 453.635

Stats. Implemented: ORS 453.605 - 453.807

DIVISION 121

LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

333-121-0001

Purpose and Scope

(1) This ~~d~~Division contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This ~~d~~Division also contains radiation safety requirements for operating irradiators. The requirements of this ~~d~~Division are in addition to other requirements of these regulations. In particular, the provisions of ~~d~~Divisions ~~333-~~100, ~~333-~~102, ~~333-~~120, and ~~333-~~111 of ~~these regulations~~chapter 333 apply to applications and licenses subject to this ~~d~~Division. Nothing in this ~~d~~Division relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(2) The regulations in this ~~d~~Division apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this ~~d~~Division.

(3) The regulations in this ~~d~~Division do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel; medical radiology or teletherapy; radiography for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural, irradiations.

Stat. Auth.: ORS 453.675

Stats. Implemented: ORS 453.675

333-121-0010

Definitions

(1) "Annually" means at intervals not to exceed one year.

(2) "Commencement of construction" means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this division that has a reasonable nexus to radiological health and safety.

(3) "Construction" means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this division that are related to radiological safety or security. The term "construction" does not include:

(a) Changes for temporary use of the land for public recreational purposes;

(b) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(c) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(d) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this division;

(e) Excavation;

(f) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(g) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(h) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(i) Taking any other action that has no reasonable nexus to radiological health and safety.

(42) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

(53) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

- | (~~64~~) "Irradiator operator" means an individual who has successfully completed the training and testing described in OAR 333-121-0300 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

- | (~~75~~) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in OAR 333-121-0300.

- | (~~86~~) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

- | (~~97~~) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

- | (~~108~~) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

- | (~~119~~) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

- | (~~120~~) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

- | (~~134~~) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

- | (~~142~~) "Sealed source" means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

- | (~~153~~) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 ~~percent~~%, as designated by the US Geological Survey.

- | (~~164~~) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675

333-121-0020

Application for a Specific License

- (1) Applications for specific licenses shall be filed on a form prescribed by the Authority and satisfy the general requirements specified in OAR 333-102-0200.
- (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 should be granted or denied or whether a license should be modified or revoked.
- (3) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.
- (4) An application for a license may include a request for a license authorizing one or more activities.
- (5) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Authority provided such references are clear and specific.
- (6) Applications and documents submitted to the Authority may be made available for public inspection except that the Authority may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Stat. Auth.: ORS 453.675
Stats. Implemented: ORS 453.675

DIVISION 122

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL X-RAY MACHINE OPERATIONS

333-122-0005

Definitions

As used in this division, the following definitions apply:

(1) "Annual refresher safety training" means a review conducted or provided by the registrant for its employees on radiation safety aspects of industrial ~~X~~-ray. The review must include, as a minimum, a review of radiation safety aspects of industrial ~~X~~-ray, any results of internal audits, Authority inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review must also provide opportunities for employees to ask safety questions.

(2) "ANSI" means the American National Standards Institute.

(3) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in OAR 333-120-0180.

(4) "Cabinet ~~X~~-ray system" means an ~~X~~-ray system with the ~~X~~-ray tube installed in an enclosure, hereinafter termed a cabinet that is independent of existing architectural structures except the floor. The cabinet ~~X~~-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of radiation. This definition includes ~~X~~-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities, and all ~~X~~-ray systems designed primarily for the inspection of letters, periodicals and packages in mailrooms. An ~~X~~-ray tube used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet ~~X~~-ray system.

(5) "Certifiable cabinet ~~X~~-ray system" means an existing uncertified ~~X~~-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

(6) "Certified cabinet ~~X~~-ray system" means an ~~X~~-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

(7) "Hands-on experience" means experience in all of those areas considered to be directly involved in the ~~X~~-ray process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, set-up of ~~X~~-ray equipment, and radiation surveys, ~~etc.~~, as applicable. Trainees undergoing the "hands-on experience" must do so under the direct supervision of a qualified industrial ~~X~~-ray machine operator.

(8) "Industrial ~~X~~-ray" means a nondestructive examination of the structure of materials using an ~~X~~-ray machine to make radiographic images.

(9) "Industrial ~~X~~-ray instructor" means any industrial ~~X~~-ray operator who has been authorized by the Authority to provide on-the-job training to industrial ~~X~~-ray trainees in accordance with OAR 333-122-0200 ~~of these rules~~.

(10) "Industrial ~~X~~-ray trainee" means any individual who, under the direct supervision of an industrial ~~X~~-ray instructor, uses industrial ~~X~~-ray machines, related handling tools or radiation survey instruments during the course of his instruction.

(11) "Industrial ~~X~~-ray operations" means all activities performed with an industrial ~~X~~-ray machine. Activities include using, setting up equipment, and any activity inside restricted area boundaries.

(12) "Industrial ~~X~~-ray personnel" means any ~~X~~-ray operator, ~~X~~-ray instructor or ~~X~~-ray trainee.

(13) "Permanent ~~X~~-ray installation" means an enclosed shielded room, cell, or vault in which industrial ~~X~~-ray is performed.

(14) "Personal supervision" means supervision in which the ~~X~~-ray operator is physically present at the site where ~~X~~-ray machines and associated equipment are being used, watching the performance of the ~~X~~-ray operator's assistant and in such proximity that immediate assistance can be given if required.

(15) "Practical examination" means a demonstration through application of the safety rules and principles in industrial ~~X~~-ray including use of all procedures and equipment to be used by industrial ~~X~~-ray personnel.

(16) "Radiation safety officer for industrial ~~X~~-ray" means an individual with the responsibility for the overall radiation safety program on behalf of the registrant and who meets the requirements of [OAR 333-122-0175](#)~~200~~ ~~of these rules~~.

(17) "Shielded room ~~X~~-ray using ~~X~~-ray machines" means an enclosed room or vault in which industrial ~~X~~-ray is performed the interior of which is not occupied during ~~X~~-ray operations. The room must be so shielded that every location on the exterior meets conditions for an unrestricted area as specified in OAR 333-120-0180, and the only access is through openings that are interlocked so that the ~~X~~-ray machine will not operate unless all openings are securely closed.

(18) "X-ray Operator" means any individual who handles, adjusts technique factors, activates the exposure switch ~~/~~ or button on an industrial ~~X~~-ray machine and is qualified under [OAR 333-122-0200](#) ~~of these rules~~.

(19) "X-ray operator's assistant" means any individual who, under the direct supervision of an industrial ~~X~~-ray operator, uses radiographic ~~X~~-ray machines, related handling tools or radiation survey instruments in industrial ~~X~~-ray.

Stat. Auth.: ORS 453.605 - 453.807

Stats. Implemented: ORS 453.605 - 453.807

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