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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED: 04/29/2026 12:21 PM
ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Radiation Protection Services: Amended X-ray and tanning operations and training rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/21/2026 5:00 PM
The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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HEARING(S)
Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/19/2026
TIME: 10:00 AM
OFFICER: Staff

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 971-277-2343
CONFERENCE ID: 295428655
SPECIAL INSTRUCTIONS:
This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register to receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 295 428 655# for audio (listen) only. This hearing will close no later than 11:00AM but may close as early as 10:30AM if everyone who signs up to provide testimony has been heard from.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S):

The Oregon Health Authority, Public Health Division, Center for Health Protection, Radiation Protection Services (RPS), is proposing amendments to Oregon Administrative Rules (OAR) to address rule compatibility with the Nuclear Regulatory Commission's federal regulations, provide better clarification regarding the definition and training requirements for a radiation supervisor, allowing a veterinarian or a veterinary technician to operate specific X-ray imaging devices, outlines the clinical hours required for a medical physicist consultant, and outlines the training and service requirements regarding the tanning registrant's operations. Proposed rule language addresses the need to provide authority for the veterinarian and veterinary technician to operate a fluoroscopy and computed tomography imaging devices, to define that a X-ray supervisor must direct work being performed by therapy staff, allows a non-radiologist practitioner to supervise fluoroscopic imaging upon completion of an Oregon Health Authority-approved training course, allows a dental practitioner who is using a rectangular collimator to be exempt from placing a thyroid collar on a pediatric patient, and reduce the amount of documented experience time required for a physicist to provide computed tomography consulting.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Oregon Revised Statutes ORS 453.605 – 453.807: https://www.oregonlegislature.gov/bills_laws/ors/ors453.html

Oregon Administrative Rules, Chapter 333, Divisions 102, 106, 116, and 119:
https://www.oregon.gov/oha/PH/HEALTHYENVIRONMENTS/RADIATIONPROTECTION/Pages/rules.aspx

Nuclear Regulatory Commission, 10 CFR Part 32.72
https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0072

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE:

Proposed rulemaking is to ensure that all Oregonians and communities are afforded equitable medical care and service delivery. Proposed rules will not affect racial equity but ensures equitable medical and preventive care to all person within the state. Radiation Protection Services is committed to the regulation of radioactive material and devices to protect all communities and persons from unnecessary exposure to radiation and engages all persons to assess the impacts of Oregon Health Authority's regulatory practices.

FISCAL AND ECONOMIC IMPACT:

RPS, licensees, and registrants will not experience any fiscal or economic impacts by the proposed rule amendments.

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

(1) There is no anticipated cost of compliance to the Oregon Health Authority or other state or local governments by amending these rules. There is no anticipated cost of compliance impact on the public.

(2)(a) RPS does not possess the data to determine with accuracy how many dental facilities, salons, fitness establishments, veterinary services, and cancer clinics providing imaging and therapy, tanning and veterinary operations using radioactive materials and electronic devices are subject to these rules. Small businesses will not be negatively fiscally or operationally impacted by these proposed amended rules.

(b) Licensees and registrants will not experience increased administrative activities with the proposed rule amendments.

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

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

Proposed amended rule language was developed with urban and rural medical professionals and tanning registrants to improve regulatory practices. In addition, RPS's Radiation Advisory Committee members representing various businesses provided support in the development of these proposed rule amendments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
333-102-0285, 333-106-0005, 333-106-0205, 333-106-0325, 333-106-0368, 333-106-0370, 333-116-1000, 333-119-0010, 333-119-0080, 333-119-0090, 333-119-0100

AMEND: 333-102-0285

RULE SUMMARY: OAR 333-102-0285 is being amended by correcting a rule reference number to Nuclear Regulatory Commission's regulation from 21 CFR 207.20 to 21 CFR 207.17

CHANGES TO RULE:

333-102-0285
Special Requirement for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material: Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceutical Drugs Containing Byproduct Material for Medical Use Under OAR Chapter 333, Division 116 ¶

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceutical drugs containing radioactive material for use by persons authorized pursuant to division 116 of this chapter may be approved if:¶
(a) The applicant satisfies the general requirements specified in OAR 333-102-0200;¶
(b) The applicant submits evidence that the applicant is at least one of the following:¶
(A) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.~~20~~17(a);¶
(B) Registered or licensed with a state agency as a drug manufacturer;¶
(C) Licensed as a pharmacy by a state Board of Pharmacy;¶
(D) Operating as a nuclear pharmacy within a federal medical institution; or¶
(E) A Positron Emission Tomography (PET) drug production facility registered with a state agency.¶
(c) The applicant submits information on the radionuclide, chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radiopharmaceutical drugs by medical use licensees; and¶
(d) The applicant commits to the following labeling requirements:¶

(A) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL; the name of the radiopharmaceutical drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceutical drugs with a half-life greater than 100 days, the time may be omitted.¶
(B) A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical drug to be transferred for commercial distribution. The label must include the radiation symbol and the words CAUTION, RADIOACTIVE MATERIAL or DANGER, RADIOACTIVE MATERIAL and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.¶
(2) A licensee described by paragraphs (1)(b)(C) or (D) of this rule:¶
(a) May prepare radiopharmaceutical drugs for medical use, as defined in OAR 333-116-0020, provided that the radiopharmaceutical drug is prepared either by an authorized nuclear pharmacist, as specified in subsections (2)(b) and (2)(d) of this rule, or an individual under the supervision of an authorized nuclear pharmacist as specified in OAR 333-116-0100.¶
(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:¶
(A) This individual qualifies as an authorized nuclear pharmacist as defined in OAR 333-116-0020;¶
(B) This individual meets the requirements specified in OAR 333-116-0910, 333-116-0760, 333-116-0915 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or¶
(C) This individual is designated as an authorized nuclear pharmacist in accordance with subsection (2)(d) of this rule.¶
(c) The actions authorized in subsections (2)(a) and (2)(b) of this rule are permitted in spite of more restrictive language in license conditions.¶
(d) May designate a pharmacist (as defined in OAR 333-116-0020) as an authorized nuclear pharmacist if:¶
(A) The individual was a nuclear pharmacist preparing only radiopharmaceutical drugs containing accelerator-produced radioactive material; and¶
(B) The individual practiced at a pharmacy at a government agency or federally recognized ~~Indian~~ Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the Nuclear Regulatory Commission (Commission).¶
(e) Shall provide to the ~~Authority~~Oregon Health Authority (Authority) a copy of:¶
(A) Each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in OAR 333-116-0910; or¶
(B) The Commission or Agreement State license; or¶
(C) Commission master materials licensee permit; or¶
(D) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or¶
(E) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized ~~Indian~~ Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the ~~NRC~~Commission; and¶
(F) A copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows pursuant to paragraphs (2)(b)(A) and (2)(b)(C) of this rule, which allows the individual to work as an authorized nuclear pharmacist.¶
(3) A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceutical drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceutical drugs prior to transfer for commercial distribution. In addition, the licensee shall:¶
(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument and make adjustments when necessary;¶
(b) Check each instrument for constancy and proper operation at the beginning of each day of use; and¶
(c) Satisfy the labeling requirements in subsection (1)(d) of this rule. ¶
(4) Nothing in this rule relieves the licensee from complying with applicable FDA, other federal and state requirements governing radiopharmaceutical drugs.¶
NOTE: Although the Authority does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radio pharmaceuticals containing radioactive material as a part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material, who desires to have the reagent kits approved by the Authority for use by persons licensed for medical use pursuant to OAR chapter 333, division 116 or by persons authorized under a group license, or equivalent, by the U.S. Nuclear Regulatory

Commission or any other Agreement State, may submit the pertinent information specified in this rule.
Statutory/Other Authority: ORS 453.635, 453.665
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-106-0005

RULE SUMMARY: OAR 333-106-0005 is being amended by updating the definition of “supervision” to include having responsibility to direct radiation work being performed, in addition to routinely reviewing and monitoring work being performed.

CHANGES TO RULE:

333-106-0005
Definitions ¶

As used in ~~this~~OAR chapter 333, division 106, 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) "Advanced practice registered nurse (APRN)" means a clinical nurse specialist, certified nurse anesthetist, or nurse practitioner licensed or state certified by the Oregon State Board of Nursing. ¶
(4) "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.¶
(5) "Applications training" means a vendor or manufacturer providing training for specific X-ray equipment.¶
(6) "A.R.R.T." means the American Registry of Radiologic Technologists.¶
(7) "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.¶
(8) "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.¶
(9) "Authority approved instructor" means an individual who has been evaluated and approved by the Oregon Health Authority to teach radiation safety.¶
(10) "Authority approved training course" means a course of training that has been evaluated and approved by the Oregon Health Authority.¶
(11) "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".)¶
(12) "Barrier" (see "Protective barrier").¶
(13) "Beam axis" means a line from the source through the centers of the X-ray fields.¶
(14) "Beam-limiting device" means a device that provides a means to restrict the dimensions of the X-ray field.¶
(15) "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.¶
(16) "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.¶
(17) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.¶
(18) "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.¶
(19) "Certified system" means any X-ray system that has one or more certified component(s).¶
(20) "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.¶
(21) "Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.¶
(22) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.¶
(23) "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.¶
(24) "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.¶
(25) "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.¶
(26) "Cooling curve" means the graphical relationship between heat units stored and cooling time.¶
(27) "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.¶
(28) "Dental therapist" means a person licensed to practice dental therapy under ORS 679.603.¶
(29) "Detector" (see "Radiation detector").¶
(30) "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.¶
(31) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.¶
(32) "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.¶
(33) "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.¶
(34) "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.¶
(35) "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").¶
(36) "Entrance exposure rate" means the exposure free in air per unit of time.¶
(37) "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.¶
(38) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.¶
(39) "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.¶
(40) "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.¶
(41) "Fluoroscopic X-ray equipment operator" means any individual who, adjusts technique factors, activates the exposure switch or button of a fluoroscopic X-ray machine or physically positions patients or animals. Human holders, used solely for immobilization purposes (example being veterinarian human holders) are excluded from this rule.¶
(42) "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.¶
(43) "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.¶
(44) "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.¶
(45) "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.¶
(46) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, example being kVp x mA x second.¶
(47) "HVL" (see "Half-value layer").¶
(48) "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.¶
(49) "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.¶
(50) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.¶
(51) "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.¶
(52) "Irradiation" means the exposure of matter to ionizing radiation.¶
(53) "Kilovolt-peak" (see "Peak tube potential").¶

(54) "kV" means kilovolts.¶
(55) "kVp" (see "Peak tube potential").¶
(56) "kWs" means kilowatt second.¶
(57) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.¶
(58) "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.¶
(59) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:¶
(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, example being 10 milliampere 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.¶
(60) "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.¶
(61) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.¶
(62) "mA" means milliampere.¶
(63) "mAs" means milliampere second.¶
(64) "Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.¶
(65) "Mobile equipment" (see "X-ray equipment").¶
(66) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and¶
(a) Are not specifically certified in diagnostic or therapeutic use of X-rays; and¶
(b) Are currently licensed by their respective Oregon licensing board.¶
(67) "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.¶
(68) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.¶
(69) "Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.¶
(70) "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.¶
(71) "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").¶
(72) "PID" (see "Position indicating device").¶
(73) "Portable equipment" (see "X-ray equipment").¶
(74) "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.¶
(75) "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.¶
(76) "Primary protective barrier" (see "Protective barrier").¶
(77) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.¶
(78) "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.¶
(79) "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.¶
(80) "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.¶
(81) "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~~al 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 Oregon Health Authority for specific activities.¶
(82) "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.¶
(83) "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.¶
(84) "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.¶
(85) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.¶
(86) "Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.¶
(87) "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~~al 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.¶
(88) "Radiologist" or "oral radiologist" means a physician or dentist trained in the diagnostic use of X-rays and who is;¶
(a) Currently licensed by their respective Oregon licensing board; and¶
(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon; or¶
(c) ABR board eligible after successfully completing the Accreditation Council for Graduate Medical Education accredited diagnostic radiology residency program.¶
(89) "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.¶
(90) "R.T." means a radiologic technologist certified in radiography and currently licensed by the Oregon Board of Medical Imaging.¶
(91) "Rating" means the operating limits as specified by the component manufacturer.¶
(92) "Recording" means producing a permanent form of an image resulting from X-ray photons.¶
(93) "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.¶
(94) "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.¶
(95) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct scattered radiation").¶
(96) "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.¶
(97) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.¶
(98) "Secondary protective barrier" (see "Protective barrier").¶
(99) "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.¶
(100) "SID" (see "Source-image receptor distance").¶
(101) "Source" means the focal spot of the X-ray tube.¶
(102) "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.¶
(103) "Spot check" means a procedure which is performed to ~~as~~ensure that a previous calibration continues to be valid.¶
(104) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.¶
(105) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.¶
(106) "SSD" means the distance between the source and the skin of the patient.¶
(107) "Stationary equipment" (see "X-ray equipment").¶
(108) "Stray radiation" means the sum of leakage and scattered radiation.¶
(109) "Supervision" means the supervising individual routinely reviews, directs 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.¶
(110) "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.¶
(111) "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.¶
(112) "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.¶
(113) "Tube" means an X-ray tube, unless otherwise specified.¶
(114) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when such are contained within the tube housing.¶
(115) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of

the technique factors.¶
(116) "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.¶
(117) "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.¶
(118) "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.¶
(119) "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.¶
(120) "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.¶
(121) "X-ray control" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as exposure switches (control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.¶
(122) "X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of equipment are as follows:¶
(a) "Mobile equipment" means X-ray equipment mounted on a permanent base with wheels and casters for moving while completely assembled and intended to be taken from one geographical location to another or from one room to another;¶
(b) "Portable equipment" means X-ray equipment designed to be hand-carried but not hand-held during operations.;¶
(c) "Stationary equipment" means X-ray equipment which is installed in a fixed location., such as bolted to the floor or wall;¶
(d) "Transportable" means X-ray equipment installed in a vehicle or trailer; and¶
(e) "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.¶
(123) "X-ray equipment operator" means any individual who handles, adjusts technique factors, activates the exposure switch/ or button of an X-ray machine, or physically positions patients or animals for a radiograph (see "Operator").¶
(124) "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.¶
(125) "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.¶
(126) "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.¶
(127) "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.¶
(128) "X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.
Statutory/Other Authority: ORS 453.605 - 453.807
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-106-0205

RULE SUMMARY: OAR 333-106-0205 is being amended by requiring a non-radiologist practitioner to receive an Oregon Health Authority approved fluoroscopy training course to operate a fluoroscopy machine or when supervising the fluoroscopy operator. The amended rule will also allow a Doctor of Veterinary Medicine licensed by the Oregon Veterinary Medical Examination Board or a veterinary technician certified by the Oregon Veterinary Medical Examination Board to operate a fluoroscopy machine after successfully completing an approved Oregon Health Authority fluoroscopy course and the manufacturer's applications training.

CHANGES TO RULE:

333-106-0205
Fluoroscopic X-ray Systems Requirements: 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 following 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~~Oregon Health Authority (Authority) approved resource that meets section (2) of this rule~~.~~, or have been operating fluoroscopic equipment prior to April 11, 2005;¶
(c) Radiologic technologists who have a permanent or temporary license from the Oregon Board of Medical Imaging (OBMI) to practice radiography;¶
(d) Physician associates who have a fluoroscopy permit from the O~~regon Board of Medical Imaging;¶~~
~~(e)~~ BMI;¶
(e) Radiology physician's assistants (R.P.A.s) and registered radiology assistants (R.R.A.s) who are licensed by the OBMI;~~ and¶~~
~~(f~~¶
(f) When activating the tube for imaging veterinary patients only, a doctor of veterinary medicine licensed by the Oregon Veterinary Medical Examination Board or veterinary technicians certified by the Oregon Veterinary Medical Examination Board that:¶
(A) Have successfully completed an Authority approved fluoroscopy course; and ¶
(B) Have completed the manufacturer's application training as defined in OAR 333-106-0005; and ¶
(g) 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) A non-radiologist practitioner that is physically present in the room during fluoroscopy use must have an Authority approved fluoroscopy training if:¶
(A) Operating a fluoroscopy machine; or¶
(B) Supervising a fluoroscopy operator.¶
(c) 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~~d) Radiologic technologists who have a permanent or temporary license from the OBMI to practice radiography may operate fluoroscopic equipment under the personal or direct supervision of a radiologist or under the personal supervision of a non-radiologist practitioner who has ~~had proper training in the use and operation of fluoroscopic X-ray equipment.¶~~
~~(d) An~~ met the training requirments in section (2) of this rule.¶
(e) An advanced practice registered nurse (APRN) who has obtained an OBMI Limited Fluoroscopy Supervision Permit may provide personal supervision to radiologic technologists who have a permanent or temporary license

issued from the OBMI to operate fluoroscopic equipment.¶
(~~e~~f) Physician associates with fluoroscopy permits may operate fluoroscopy equipment without supervision if they have entered into a collaborative agreement with a physician, podiatric physician or employer.¶
(~~f~~g) R.R.A.s or R.P.A.s may operate fluoroscopic equipment under the direct supervision of a radiologist.¶
(~~g~~h) Physician associates licensed with the Oregon Medical Board while completing specific clinical experience pre-requisites to become eligible to take the OBMI fluoroscopy permit examination, may operate fluoroscopy equipment under personal supervision of the physician associate's supervising physician, licensed radiologist, licensed radiographer or medical physicist.¶
(~~h~~i) 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 a~~n~~ radiologic technologist (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 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.
Statutory/Other Authority: ORS 453.605 - 453.807
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-106-0325

RULE SUMMARY: OAR 333-106-0325 is being amended by allowing the use of a rectangular collimator with a positioning indicating device. Proposed rule language will direct the registrant to have all collimators installed by an Oregon Health Authority licensed vendor. Amending this rule will allow dental providers to not be required to apply a leaded thyroid collar to a pediatric patient during intraoral X-ray exposures.

CHANGES TO RULE:

333-106-0325
Additional Requirements for Radiographic Machines: 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 18~~cm~~ centimeters.¶
(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 or rectangular cone 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 or rectangular cone having a diameter of no more than six centimeters.¶
(A) A positioning indicating device (PID) must be used for all exposures when using a rectangular collimator.¶
(B) All rectangular collimators must be installed by an Oregon Health Authority licensed vendor. ¶
(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 (Tmax - Tmin).¶
(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.¶
(B) An X-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.¶
(C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "0".¶
(4) Radiation Exposure Control Location and Operator Protection. Each X-ray control must be located in such a way as to meet the following requirements:¶
(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(78), 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.¶
(5) Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held

constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (Emax) minus the minimum exposure (Emin): E >5 (Emax - Emin)¶
(6) Accuracy.¶
(a) Deviation of technique factors from the indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer.¶
(b) kVp Limitations. Dental X-ray machines with a nominal fixed kVp of less than 55 kVp shall not be used to make diagnostic dental radiographs on humans.¶
(7) Administrative Controls.¶
(a) Patient and film holding devices shall be used when the techniques permit;¶
(b) The tube housing and the PID shall not be hand-held during an exposure;¶
(c) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of section (2) of this rule or its updated version; ¶
(d) All pediatric patients shall wear a 0.25 m~~m~~illimeter lead equivalent thyroid collar to protect the thyroid during intraoral X-ray exposures~~;~~. Registrants who meet the requirements in paragraphs (2)(b)(A) and (B) of this rule are not required to apply the thyroid collar to a pediatric patient. ¶
(e) Dental fluoroscopy without image intensification shall not be used; and¶
(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Oregon Health Authority (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 m~~m Pb~~illimeter lead 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 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(9) before using a hand-held unit. Training on the safe use of the unit shall be documented and include at a minimum:¶
(A) Proper positioning of the unit to ensure an adequate protected position;¶
(B) Limitations on the use of position indicating devices that require longer distances to the patient's face;¶
(C) Diagrams such as drawings, illustrations, or schematics of protected position and location in relationship to the unit;¶
(D) Diagrams such as drawings, illustrations, or schematics of the effect of improper distance or removal of shielding device; and¶
(E) Diagrams such as drawings, illustrations, schematics of common examples of improper positioning of the unit and or location of the operator.¶
(d) An appropriate receptor holder must be used during the X-ray exposure.¶
(e) A PID must be used during the X-ray exposure.¶
(f) A hand-held unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize the hand-held unit during a patient examination.
Statutory/Other Authority: ORS 453.605 - 453.807
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-106-0368

RULE SUMMARY: OAR 333-106-0368 is being amended by requiring medical physicists to be qualified for providing computed tomography (CT) X-ray system surveys and consultative service by completing 200 hours of documented experience in a clinical CT environment within a two-year period. Current rule requires the individual to complete three years of documented experience. The proposed rule amendment will allow for less restrictive requirements for a medical physicist to be eligible to provide CT services.

CHANGES TO RULE:

333-106-0368
Computed Tomography (CT) X-ray Systems: Qualified CT Medical Physicist ¶

In order to perform a computed tomography (CT) survey or provide consultative services on a CT unit, a person must be approved by the ~~Authority~~Oregon Health Authority (Authority), under the provisions of OAR 333-101-0020, as a provider of radiation services in CT. In addition, the qualified CT medical physicist shall meet the requirements outlined below:¶
(1) Initial qualifications. Before beginning to provide consultation to a CT facility, a medical physicist shall meet one of the following:¶
(a) Be certified in diagnostic radiological physics or radiological physics by the American Board of Radiology, or in diagnostic imaging physics by the American Board of Medical Physics, or in diagnostic radiology physics by the Canadian College of Physicists in Medicine; or¶
(b) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or similar topics related to the practice of medical physics, and have ~~three yea~~200 hours of documented experience in a clinical CT environment within two years. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. ~~d~~Department of ~~e~~Education (USDE) or by the ~~c~~Council for ~~h~~Higher ~~e~~Education ~~a~~Accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the USA; or¶
(c) CT medical physicists who, prior to August 1, 2014, have been actively working in the area of CT in the State of Oregon and are specifically approved by the Authority to provide CT medical physics services in Oregon, are exempt from the requirements in subsections (a) and (b) this section.¶
(2) Continuing experience. After the second anniversary of the date when the requirements of section (1) of this rule were completed, the medical physicist shall have evaluated at least two CT scanners in the prior 24-month period.¶
(3) Continuing education. After the third anniversary of the date when the requirements of section (1) of this rule were completed, the CT medical physicist shall have earned at least 15 continuing medical education units; at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.¶
(4) Re-establishing qualifications. A CT medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:¶
(a) A CT medical physicist who fails to meet the continuing experience requirements of section (2) of this rule shall evaluate two CT scanners under the supervision of a medical physicist, to meet the requirements of section (2) of this rule.¶
(b) A CT medical physicist who fails to meet the continuing education requirements of section (3) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of section (3) of this rule.¶
(5) Documentation of continuing education and continuing experience shall be kept on file and made available to an inspector upon request.
Statutory/Other Authority: ORS 453.605 - 453.807
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-106-0370

RULE SUMMARY: OAR 333-106-0370 is being amended by allowing a Doctor of Veterinary Medicine licensed by the Oregon Veterinary Medical Examination Board or a veterinary technician certified by the Oregon Veterinary Medical Examination Board to operate a computed tomography (CT) X-ray system. The registrant must successfully complete an Oregon Health Authority approved CT course and manufacturer's application training. This amended rule is proposed due to the volume of rule exemptions received from the veterinary industry and to instead impose certain standards to allow for operation without obtaining an exemption.

CHANGES TO RULE:

333-106-0370
Computed Tomography X-ray Systems: Operator Requirements ¶

(1) Computed ~~T~~tomography (CT) X-ray systems shall be operated by individuals who are authorized to operate CT in accordance with the statutes and rules of the Oregon Board of Medical Imaging.¶
(2) A ~~CB~~cone beam CT scanner shall be operated by a dentist, hygienist, dental assistant or an individual that meets the requirements in section (1) of this rule after completing a machine specific manufacturer operator training program.~~-~~¶
(3) A mini-CT machine shall be operated by an ear, nose and throat physician or individual who meets the requirements of section (1) of this rule for otolaryngology imaging after completing a machine specific manufacturer operator training program.¶
(4) Veterinary CT systems, only for imaging veterinary patients, may only be operated by a doctor of veterinary medicine licensed by the Oregon Veterinary Medical Examining Board or veterinary technicians certified by the Oregon Veterinary Medical Examining Board who: ¶
(a) Have successfully completed an Oregon Health Authority approved CT course; and ¶
(b) Have completed the manufacturer's application training as defined in OAR 333-106-0005.
Statutory/Other Authority: ORS 453.605 - 453.807
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-116-1000

RULE SUMMARY: OAR 333-116-1000 is being amended by adding rule language outlying the reporting requirements of medical events resulting from patient intervention resulting in unintended permanent organ damage. Rule language is being inserted into the rule to be compatible with the Nuclear Regulatory Commission's 10 CFR Part 3045.

CHANGES TO RULE:

333-116-1000
Report and Notification of a Medical Event ¶

(1) A licensee must report any medical event, except for an event that results from patient intervention, in which:¶
(a) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in:¶
(A) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; ~~and~~or¶
(i) The total dose delivered differs from the prescribed dose by 20 percent or more;¶
(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or¶
(iii) The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.¶
(B) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:¶
(i) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;¶
(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;¶
(iii) An administration of a dose or dosage to the wrong individual or human research subject;¶
(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or¶
(v) A leaking sealed source.¶
(C) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:¶
(i) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and¶
(ii) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.¶
(b) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:¶
(A) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;¶
(B) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or¶
(C) An administration of a source that includes any of the following: ¶
(i) The wrong radionuclide;¶
(ii) The wrong individual or human research subject;¶
(iii) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or¶
(iv) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.¶
(2) A licensee shall report any event resulting from intervention of a patient or human research subject where the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.¶
(3) The licensee must notify by telephone the Oregon Health Authority (Authority) no later than the next calendar day after discovery of the medical event.¶
(~~3~~4) The licensee must submit a written report to the Authority within 15 days after discovery of the medical event.¶
(a) The written report must include:¶
(A) The licensee's name;¶
(B) The name of the prescribing physician;¶
(C) A brief description of the event;¶
(D) Why the event occurred;¶

(E) The effect, if any, on the individual(s) who received the administration;¶
(F) What actions, if any, have been taken or are planned to prevent recurrence; and¶
(G) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.¶
(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.¶
(~~4~~5) The licensee must provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee must inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee must provide such a written description if requested.¶
(~~5~~6) Aside from the notification requirement, nothing in this ~~section~~rule affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.¶
(~~6~~7) A licensee shall:¶
(a) Maintain a copy of the report described in section (~~3~~4) of this rule and annotate as follows:¶
(A) Name of the individual who is the subject of the event; and¶
(B) Identification number, or if no other identification number is available, the Social Security number of the individual who is the subject of the event.¶
(b) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.
Statutory/Other Authority: ORS 453.635
Statutes/Other Implemented: ORS 453.605 - 453.807

AMEND: 333-119-0010

RULE SUMMARY: OAR 333-119-0010 is being amended by removing subsections (a) through (k) from the tanning operator definition. The rule is now amended to demonstrate that the operator must meet requirements in OAR 333-119-0080 which is being proposed to outline the operator training requirements. Current rule language defines a tanning operator but does not outline the training requirements to become an operator.

CHANGES TO RULE:

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 ~~T~~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.¶
(8) "Handrails" means a suitable physical aid that will help to maintain proper exposure distance.¶
(9) "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.¶
(10) "Individual" means any human being.¶
(11) "Minor" means any individual under the age of 18 years old.¶
(12) "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 informatio~~successfully completed an Oreg~~arding 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;¶~~
~~(i) Instructing the customer in the proper use of protective eyewear;¶~~
~~(j) Verifying and documenting age of clients; and¶~~
~~(k) Sanitizing tanning devices~~on Health Authority licensed tanning training course outlined in OAR 333-119-0080.¶
(13) "Other ~~C~~compensation" means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.¶
(14) "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.¶
(15) "Phototherapy ~~D~~device" means equipment that emits ultraviolet radiation used by a health care professional

in the treatment of disease or illness.¶
(16) "Program" means the Radiation Protection Services section of the Public Health Division in the Oregon Health Authority.¶
(17) "Protective Eeyewear" means suitable eyewear that protects the eye from ultraviolet radiation and allows adequate vision.¶
(18) "Public Pplaces" means the area where members of the public may assemble and are not directly affected by tanning operations.¶
(19) "Recommendation" means a written directive using a form provided by the Authority and signed by a licensed physician.¶
(20) "Registrant" means a tanning facility registered with the Authority as required by provisions of this division.¶
(21) "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.¶
(23) "Safe Llevel" means not more than 50 colonies of microorganisms per four square inches of equipment surface.¶
(24) "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.¶
(25) Skin Ttypes:¶
(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.¶
(27) "Tanning Ddevice" 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.¶
(28) "Tanning Ffacility" means any location, place, area, structure, or business that provides persons access to any tanning device.¶
(29) "Timer" means an electronic device designed specifically to terminate tanning sessions at a preset time interval.¶
(30) "Ultraviolet Rradiation" means radiation that has a wavelength between two hundred nanometers and four hundred nanometers.
Statutory/Other Authority: ORS 431.925 - 431.955
Statutes/Other Implemented: ORS 431.925 - 431.955

AMEND: 333-119-0080

RULE SUMMARY: OAR 333-119-0080 is being amended to add specific training requirements that the vendor must address in their training curriculums for courses to be approved by the Oregon Health Authority. Content from the definition of operator (OAR 333-119-0010) was moved to this rule to outline the training requirements that the vendor must provide to the participant.

CHANGES TO RULE:

333-119-0080
Specific Requirements: Training of Personnel ¶

(1) The registrant shall ensure that tanning devices are operated only while an adequately trained operator is present at the tanning facility.¶
(2) All operators of registered tanning devices must successfully complete an ~~Authority~~Oregon Health Authority (Authority) approved tanning training course 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 a~~Prior to course approval the applicant must submit a curriculum to include, at a minimum, content covering the following topics, as well as any other topic determined by the Authority:¶
(a) Understanding ultraviolet radiation;¶
(b) The skin;¶
(c) The tanning process;¶
(d) Risks of overexposure to ultraviolet radiation;¶
(e) Minimal erythemal dose and minimal melanogenic dose;¶
(f) Skincare;¶
(g) Determining the suitability for use of a tanning device;¶
(h) Tanning lamps;¶
(i) Providing information regarding the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing agents;¶
(j) Utilization of the Fitzpatrick Skin Type Scale to determine customer's skin type and exposure schedule;¶
(k) Maintaining and documenting required exposure records;¶
(l) Recognizing and reporting injuries or alleged injuries to the registrant;¶
(m) Setting timers which control the duration of exposure;¶
(n) Instructing the customer in the proper use of protective eyewear;¶
(o) Sanitizing tanning devices;¶
(p) U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) regulations; ¶
(q) Oregon Administrative Rules of chapter 333, division 119; and¶
(r) Any other topic determined by the Authority to be critical to client protection.
Statutory/Other Authority: ORS 431.925 - 431.955
Statutes/Other Implemented: ORS 431.930

AMEND: 333-119-0090

RULE SUMMARY: OAR 333-119-0090 is being amended to make a rule reference number correction from OAR 333-119-0100(14)(b) to 333-119-0100(12).

CHANGES TO RULE:

333-119-0090
Specific Requirements: Protection of Consumers ¶

The registrant and operators are responsible for protecting the customers from overexposure to ~~U~~ultraviolet ~~L~~light by ensuring that:¶
(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~~2).¶
(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"¶
(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 device manufacturer's recommendations. 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.¶
(9) Tanning operators shall maintain a list of the common photosensitizing agents as provided by the ~~Public~~Oregon Health ~~Divis~~Authority, U.S. Food and Drug Administration~~,~~ (FDA), or other appropriate authorities, available for review by customers.¶
(10) Tanning facilities are prohibited from controlling the use of tanning devices solely with token timer systems or a mechanical timer system.
Statutory/Other Authority: ORS 431.925 - 431.955
Statutes/Other Implemented: ORS 431.930

AMEND: 333-119-0100

RULE SUMMARY: 333-119-0100 is being amended to ensure that an electrical supply system installation or repair to a tanning device is performed by a State of Oregon licensed electrician.

CHANGES TO RULE:

333-119-0100
Specific Requirements: 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 tanning device shall be labeled in accordance with 21 CFR Part 1040.¶
(3) Adequate means shall be provided to enable a customer to summon assistance from the exposure position.¶
(4) All persons hired for ~~servicing and repair of~~electrical supply servicing to tanning devices shall be a State of Oregon licensed electrician~~s.~~. ¶
(5) State of Oregon electrical codes must be ~~observed~~complied with during service and repair actions.¶
(6) Replacement lamps shall be certified by the manufacturer as equivalent to the original lamp type as specified by the manufacturer~~,~~ or certified as an equivalent lamp per 21 CFR 1040.20.¶
(7) 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 for review by the Authority during inspections.¶
(8) Lamps removed from a tanning device 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.¶
(9) If the ultraviolet 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 ultraviolet radiation of persons not using the device.¶
(10) Each tanning device shall have a timer that complies with the requirements of 21 CFR Part 1040, Section 1040.20 (c)(2).¶
(11) The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time, or 20 minutes, whichever is less.¶
(12) A tanning facility shall use the following exposure schedule for tanning devices originally designed with a 30 minute maximum exposure time that have been reduced to a 20 minute maximum exposure time. A copy of this exposure schedule must be affixed to the tanning device, and a copy maintained at the timer controls.¶
(a) Skin type 1:¶
(A) Week 1: 1-3 minutes;¶
(B) Week 2: 4-6 minutes;¶
(C) Week 3: 7-10 minutes;¶
(D) Week 4: 11-15 minutes.¶
(b) Skin type 2 and 3:¶
(A) Week 1: 4 minutes;¶
(B) Week 2: 8 minutes;¶
(C) Week 3: 12 minutes;¶
(D) Week 4: 16 minutes;¶
(E) Weekly maintenance: 20 minutes.¶
(c) Skin Type 4 and 5:¶
(A) Week 1: 4 minutes;¶
(B) Week 2: 12 minutes;¶
(C) Week 3: 16 minutes;¶
(D) Week 4: 20 minutes;¶
(E) Weekly maintenance: 20 minutes.¶
(13) Tanning device timers shall be controlled by a 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.
Statutory/Other Authority: ORS 431.925 - 431.955
Statutes/Other Implemented: ORS 431.655, 431.930, 431.945