OREGON ADMINISTRATIVE RULES
DEPARTMENT OF HUMAN SERVICES, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 106

X-RAYS IN THE HEALING ARTS

333-106-0005
Definitions
As used in this division, the following definitions apply:
(1) "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.
(2) "Added Filtration" means any filtration that is in addition to the inherent filtration.
(3) "Aluminum Equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.
NOTE: The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.
(4) "Agency approved Instructor," means an individual who has been evaluated and approved by the Agency to teach Radiation Safety.
(5) "Agency approved training course" means a course of training that has been evaluated and approved by the Agency.
(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) "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".)
(10) "Barrier" (see "Protective Barrier").
(11) "Beam Axis" means a line from the source through the centers of the x-ray fields.
(12) "Beam-Limiting Device" means a device that provides a means to restrict the dimensions of the x-ray field.
(13) "Beam Monitoring System" means a system designed to detect and measure the radiation present in the useful beam.
(14) "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.
(15) "Cephalometric Device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(16) "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.
(17) "Certified System" means any x-ray system that has one or more certified component(s).
(18) "Changeable Filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
(19) "Coefficient of Variation (C)" means the ratio of the standard deviation to the mean value of a set of observations.
(20) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.
(21) "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.
(22) "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.
(23) "Cooling Curve" means the graphical relationship between heat units stored and cooling time.
(24) "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.
(25) "Detector" (see "Radiation detector").
(26) "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.
(27) "Diagnostic Source Assembly" means the tube housing assembly with a beam-limiting device attached.
(28) "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.
(29) "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.
(30) "Direct Scattered Radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").
(31) "Direct supervision" means that the person who directs the x-ray or fluoroscopic equipment operator(s) shall be present in the room while the individual operates the equipment.
(32) "Entrance Exposure Rate" means the exposure free in air per unit of time.
(33) "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.
(34) "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
(35) "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.

(36) "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.
(37) "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 (i.e. veterinarian human holders) are excluded from this rule.
(38) "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.
(39) "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.
(40) "General supervision" means that the person who directs the x-ray or fluoroscopic equipment operator(s), must be immediately available by telephone, pager, or other mode of communication, to provide direction if needed or requested.
(41) "Gonad Shield" means a protective barrier for the testes or ovaries.
(42) "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.
(43) "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.
(44) "Heat Unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.
(45) "HVL" (see "Half-value layer").
(46) "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.
(47) "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.
(48) "Indirect supervision" means that the person who directs the x-ray or fluoroscopic equipment operator(s) be readily available on facility premises when the x-ray or fluoroscopic equipment is operated.
(49) "Inherent Filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
(50) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
(51) "Irradiation" means the exposure of matter to ionizing radiation.
(52) "Kilovolt-Peak" (see "Peak tube potential").
(53) "kV" means kilovolts.
(54) "kVp" (see "Peak tube potential").

(55) "kWs" means kilowatt second.
(56) "Lead Equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
(57) "Leakage Radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:
(a) The useful beam; and
(b) Radiation produced when the exposure switch or timer is not activated.
(58) "Leakage Technique Factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:
(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 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.
(59) "Light Field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
(60) "Line-Voltage Regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential.
(61) "mA" means milliampere.
(62) "mAs" means milliampere second.
(63) "Maximum Line Current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
(64) "Mobile Equipment" (see "X-Ray Equipment").
(65) "Non-radiologist practitioner" means an individual who practices medicine as a medical doctor (M.D.), doctor of osteopathic medicine (D.O), doctor of chiropractic medicine (D.C.), doctor of podiatric medicine (D.P.M.) or doctor of veterinary medicine (D.V.M.); and
(a) Are not specifically certified in diagnostic and/or therapeutic use of x-rays; and
(b) Are currently licensed by their respective Oregon licensing board.
(66) "Operator" means an individual who, under the supervision of a practitioner of the healing arts, handles ionizing radiation equipment, physically positions patients or animals, determines exposure parameters or applies the radiation for the diagnostic or therapeutic purposes intended. ~~uses ionizing radiation upon a human being for diagnostic or therapeutic purposes including the physical positioning of the patient, the determination of exposure parameters, and the handling of ionizing radiation equipment~~.
(67) "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

(68) "Peak Tube Potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
(69) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.
(70) "Photo timer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is a part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
(71) "PID" (see "Position indicating device").
(72) "Portable Equipment" (see "X-Ray Equipment").
(73) "Position Indicating Device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
(74) "Primary Dose Monitoring System" means a system which will monitor useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.
(75) "Primary Protective Barrier" (see "Protective barrier").
(76) "Protective Apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
(77) "Protected Area" means an area shielded with primary or secondary protective barriers or an area removed from the radiation source such that the exposure rate within the area due to normal operating procedures and workload does not exceed any of the following limits:
(a) 2 milliroentgens (mR) in any one hour; or
(b) 100 mR in any one year.
(c) See OAR 333-120-0180 for additional information.
(78) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
(a) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure;
(b) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
(79) "Protective Glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
(80) "Qualified Expert" means an individual, approved by the Agency, who has demonstrated, pursuant to these rules, that he/she possesses the knowledge, skills, and training to measure ionizing radiation, to evaluate radiation parameters, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:
(a) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or
(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the 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 Agency for specific activities.
(81) "Quality Control Program" means a program directed at film processing and radiographic image quality whereby periodic monitoring of film processing is performed. Test films are compared against control film, either visually or by use of a densitometer, to determine if density or contrast have changed. Steps can then be taken to investigate such change and correct the problem. The x-ray machine itself can also be involved in the quality control program, as can other components of the imaging chain.
(82) "Radiation Detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
(83) "Radiation Therapy Simulation System" means a radiographic or fluoroscopic system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
(84) "Radiograph" means an image receptor on which the image is created directly or indirectly by a pattern and results in a permanent record.
(85) "Radiographic Imaging System" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.
(86) "Radiological Physicist" means an individual who:
(a) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or
(b) Has a bachelor's degree in one of the physical sciences or engineering and three years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or
(c) Has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.
(87) "Radiologist" or "Oral Radiologist" means a physician or dentist trained in the diagnostic and/or therapeutic use of x-rays and who is;
(a) Currently licensed by their respective Oregon licensing board; and
(b) Board certified by the American Board of Radiology (ABR) or American Osteopathic Board of Radiology (AOBR) or American Chiropractic Board of Radiology (DACBR) or Royal College of Physicians and Surgeons of Canada (RCPSC) or the American Board of Oral and Maxillo-Facial Radiology (ABOMFR) and currently licensed to practice medicine or dentistry in Oregon.
(88) "Radiology Physician's Assistant" (R.P.A.)/ "Registered Radiology Assistant" (R.R.A.).
(a) An R.P.A. means an American Registry of Radiologic Technologists (A.R.R.T.) technologist who has successfully completed an advanced training program and is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA).

(b) An R.R.A means an A.R.R.T. technologist who has successfully completed an advanced training program and is certified by A.R.R.T.
(89) "R.T." means a radiologic technologist certified in radiography ~~and currently registered with the A.R.R.T~~ and currently licensed by the Oregon Board of Radiologic Technology (OBRT).
(90) "Rating" means the operating limits as specified by the component manufacturer.
(91) "Recording" means producing a permanent form of an image resulting from x-ray photons.
(92) "Registrant," as used in this division, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans, animals or materials to the useful beam of the system and is required by the provisions contained in divisions 100 and 101 of this chapter to register with the Agency.
(93) "Response Time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero, sufficient to provide a steady state midscale reading.
(94) "Scattered Radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct Scattered Radiation").
(95) "Screening" means the use of a systematic approach to obtain cursory examinations of a person or group of persons without regard to specific clinical indications.
(96) "Secondary Dose Monitoring System" means a system which will terminate irradiation in the event of failure of the primary system.
(97) "Secondary Protective Barrier" (see "Protective barrier").
(98) "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
(99) "SID" (see "Source-image receptor distance").
(100) "Source" means the focal spot of the x-ray tube.
(101) "Source-Image Receptor Distance" means the distance from the source to the center of the input surface of the image receptor.
(102) "Spot Check" means a procedure which is performed to assure that a previous calibration continues to be valid.
(103) "Spot Film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
(104) "Spot-Film Device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
(105) "SSD" means the distance between the source and the skin of the patient.
(106) "Stationary Equipment" (see "X-Ray Equipment").
(107) "Stray Radiation" means the sum of leakage and scattered radiation.
(108) "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.
(109) "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.
(110) "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.
(111) "Tube" means an x-ray tube, unless otherwise specified.
(112) "Tube Housing Assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
(113) "Tube Rating Chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
(114) "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) 2 mR in any one hour; or
(b) 100 mR in any 7 consecutive days; or
(c) 500 mR in any one year.
(115) "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.
(116) "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.
(117) "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.
(118) "Wedge Filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.
(119) "X-Ray Control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as exposure switches (control), timers, photo timers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.
(120) "X-Ray Equipment" means an x-ray system, subsystem, or component thereof. Types of equipment are as follows:
(a) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;
(b) "Portable equipment" means x-ray equipment designed to be hand-carried;
(c) "Stationary equipment" means x-ray equipment which is installed in a fixed location;
(d) "Transportable" means x-ray equipment installed in a vehicle or trailer.
(121) "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”)

(122) "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.
(123) "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.
(124) "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.
(125) "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.
(126) "X-Ray Tube" means any electron tube which is designed to be used primarily for the production of x-rays.
[ED. NOTE: Equations referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

General Requirements

333-106-0010
Administrative Controls
(1) The registrant shall be responsible for directing the operation of the X-ray system(s) under ~~his~~ their administrative control. The registrant or the registrant's agent shall assure that the requirements of this section are met in the operation of the X-ray system(s).
(2) An X-ray system and/or the operation of the X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes.
(3) For X-ray equipment manufactured after July 31, 1974, the registrant shall assure that the equipment will remain in compliance with the **Code of Federal Regulations, Title 21.**
[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.752 – 453.775

333-106-0035
Deliberate Exposures Restricted
Persons shall not be exposed to the useful beam except for healing art purposes until the patient has been evaluated, and a medical need for the x-ray/s is determined, and has been authorized by a physician licensed to practice the healing arts in Oregon. Any useful diagnostic information obtained from each exposure shall be reviewed by a practitioner

of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
(1) Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.
(2) Exposure of an individual for the purpose of healing arts screening:
(a) Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency;
(b) When requesting such approval, that person shall submit the following information. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified:
(A) Name and address of the applicant and, where applicable, the names and addresses of agents within this state;
(B) Diseases or conditions for which the X-ray examinations are to be used in diagnoses;
(C) A detailed description of the X-ray examinations proposed in the screening program;
(D) Description of the population to be examined in the screening program, i.e., age, sex, physical conditions, and other appropriate information;
(E) An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations;
(F) An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these rules;
(G) A description of the diagnostic film quality control program;
(H) A copy of the technique chart for the X-ray examination procedures to be used;
(I) The qualifications of each individual who will be operating the X-ray system(s);
(J) The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;
(K) The name and address of the individual who will interpret the radiograph(s);
(L) A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;
(M) A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.
(3) Mammography screening shall be exempt from the requirements of section (2) of this rule if the following conditions are met:
(a) The requirements set forth in OAR 333-106-0700 to 333-106-0750 of these rules are satisfied.
(b) All other applicable rules are met.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0040
Patient Holding and Restraint
When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be provided and used when the technique permits. The safety rules, required by OAR 333-106-0020 of these rules, shall list individual projections where holding devices cannot be used.
(2) Written safety procedures, as required by OAR 333-106-0020 of these rules, shall indicate the requirements for selecting a holder and the procedure the holder shall follow.
(3) The human holder shall be protected, as required by OAR 333-106-0025(1) and (2) of these rules.
(4) No individual shall be used routinely to hold film or patients.
(5) Occupationally exposed personnel are prohibited from holding human patients during radiographic examination.
(6) The Agency may require a separate record to be maintained which would include the name of the human holder, date of the examination, number of exposures and technique factor used for the exposure(s).
(7) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest exposed to the useful beam shall be protected by not less than 0.5 mm lead equivalent material.
(8) Holding of patients shall be permitted only when it is otherwise impossible to obtain the necessary radiograph.
(9) Individuals stressing joints shall be exempt from section (5) of this rule.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0045
Use of Best Procedures and Equipment
Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include, but is not limited to:
(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, see **Tables 1**, **2** and **3**. The referenced tables are available on the Agency's website: http://oregon.gov/DHS/ph/rps/index.shtml.
(3) Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.
(4) X-ray systems subject to OAR 333-106-0301(1) shall not be utilized in procedures where the source to patient distance is less than 30 centimeters (cm).
(5) Cardboard cassettes without screens shall not be used (dental intraoral excluded).
(6) The number of radiographs taken for any radiographic examination should be the minimum number needed to adequately diagnose the clinical condition.
(7) Use of techniques designed to compensate for anatomical thickness variations after the primary beam has exited the patient is specifically prohibited. This includes "split screen" imaging techniques whereby multiple speed intensifying screens are placed in the same cassette, or any techniques which rely on attenuation of secondary (remnant) radiation for compensatory purposes. Lead lined grids, which are designed to reduce scattered radiation are excluded from this provision.
(8) Filter slot covers shall be provided for the x-ray operator's protection.

(9) Facilities shall determine or cause to be measured the typical patient exposure for their most common radiographic examinations. The exposures shall be recorded as milliroentgens measured in free air at the point of skin entrance for an average patient. These exposure amounts must then be compared to existing guidelines and rules, and if they exceed such guidelines or rules, action must be taken to reduce the exposure while at the same time maintaining or improving diagnostic image quality. In addition, typical patient exposure values shall be posted in the radiographic examination rooms so that they are readily available to administrators, X-ray operators, patients and practitioners.
(10) Protective equipment including aprons, gloves and shields shall be checked annually for defects, such as holes, cracks and tears to assure reliability and integrity. A record of this test shall be made and maintained for inspection by the Agency. If such defect is found, equipment shall be replaced or removed from service until repaired. Fluoroscopy shall only be used for this purpose if a visual and manual check indicated a potential problem.
(11) Dental x-ray machines designed and manufactured to be used for dental purposes shall be restricted to dental use only.
(12) An x-ray quality control program shall be implemented when required by the Agency.
(13) All x-ray equipment must be capable of functioning at the manufacturer's intended specifications.
(14) All patients' radiographic images or copies shall be made available for review by any practitioner of the healing arts, currently licensed by the appropriate Oregon licensing board, upon request of the patient.
(15) Requirements for the operation of fluoroscopic x-ray equipment. The operation of fluoroscopic equipment shall be restricted to the following categories of properly trained operators:
(a) Radiologists;
(b) Non-Radiologist practitioners with proper training in the operation and use of fluoroscopic X-ray equipment;
(c) R.T.'s, must be ARRT registered and in good standing with the OBRT;
(d) R.P.A.'s and R.R.A.'s;
(e) Technologists, who have successfully completed an OBRT approved program in radiologic technology as defined in ORS 688.405, may temporarily operate fluoroscopic equipment while waiting to take the A.R.R.T. registry examination:
(A) The temporary period will expire when the individual has passed the registry examination and is considered an R.T.; or
(B) One year from the date when the technologist completed his/ her training, provided; and
(C) The technologist, while in the temporary status referred to in section (15)(e) of this rule, has a current temporary license issued by the OBRT.
(f) The operation of fluoroscopic equipment by R.T.'s, or R.P.A.'s or R.R.A.'s shall be performed under the supervision of a radiologist and is restricted to the healing arts exclusively for the purpose of localization and/or to assist physicians in obtaining images for diagnostic purposes.
(g) Where direct or indirect supervision by a radiologist is impractical, a non-radiologist practitioner who has had proper training in the use and operation of fluoroscopic x-ray

equipment is permitted to supervise an R.T. operating fluoroscopic equipment provided that the registrant arranges to have a radiologist or Medical or Health physicist to assist in;
(A) Developing fluoroscopic and radiation safety policies and procedures;
(B) Conducting an on-site practical evaluation of the Non-Radiologist practitioner's knowledge of radiation safety practices and ability to operate the fluoroscopic equipment; and
(C) At least annually, review the registrant's fluoroscopy program. The review should include an evaluation of the fluoroscopic on-times Quality Assurance reports, condition of fluoroscopic equipment and compliance with current rules. The registrant shall correct any deficiencies noted by the review.
(h) The operation of fluoroscopic equipment by a R.T. is restricted to the healing arts exclusively for the purpose of localization and/or to assist physicians in obtaining images for diagnostic purposes.
(i) Students currently enrolled in an approved school of Radiologic Technology as defined in ORS 688.405, may only operate fluoroscopic equipment under the direct supervision of a Radiologist or a R.T. while in the clinical phase of training.
(j) Students currently enrolled in an Agency approved R.P.A. or R.A. training program, may only operate fluoroscopic equipment under the direct or in-direct supervision of a Radiologist during their clinical phase of training.
(k) Overhead fluoroscopy is not to be used as a positioning tool for radiographic examinations except for those fluoroscopic examinations specified in the registrant's written policies/procedures for fluoroscopy.
(l) Proper training in the operation of fluoroscopic X-ray equipment shall include but not be limited to the following:
(A) Principles and operation of the fluoroscopic x-ray machine;
(i) Generating x-rays;
(ii) kVp and mA;
(iii) Image intensification;
(iv) High level control versus standard operating mode;
(v) Magnification (multi-field);
(vi) Automatic Brightness Control (ABC);
(vii) Pulsed versus Continuous x-ray Dose Rates;
(viii) Image recording modes;
(ix) Imaging Systems (TV and Digital);
(x) Contrast, noise and resolution;
(B) Radiation units;
(i) Traditional units;
(ii) SI units;
(iii) Dose Area Product;
(C) Typical fluoroscopic outputs;
(i) Patient skin entrance dose;
(ii) Standard Roentgen per minute (R/min) dose rates;
(iii) High level/Boost enable Roentgen per minute (R/min) dose rates;
(D) Dose reduction techniques for fluoroscopy;
(i) The use of collimation;

(ii) X-ray tube and Image intensifier placement;
(iii) Patient size versus Technique selection;
(iv) Use of grid;
(v) Use of last image hold;
(vi) Additional beam filtration;
(vii) Alternate gantry angles;
(viii) Use of spacer cone;
(ix) Pulsed fluoroscopy;
(E) Factors affecting personnel dose;
(i) Patient dose;
(ii) Scatter radiation;
(iii) Tube and Image intensifier placement;
(iv) Time, distance and shielding;
(F) Protective devices;
(i) Lead aprons and gloves;
(ii) Thyroid collars;
(iii) Protective glasses;
(iv) Leaded drapes;
(v) Bucky slot cover;
(vi) Protective shields/barriers;
(G) Radiation exposure monitoring;
(i) Personnel monitors;
(ii) Placement of personnel monitors;
(iii) Occupational and non-occupational dose limits;
(H) Biological effects of x-ray radiation;
(i) X-rays and particulate matter;
(ii) Absorption variables (field size, dose rate, etc.);
(iii) Scatter radiation;
(iv) Cell sensitivity;
(v) Acute effects;
(vi) Latent effects;
(I) Applicable regulations;
(i) Federal; and
(ii) Oregon Rules for the Control of Radiation to include, but not limited to, divisions 101, 103, 106, 111 and 120.
(16) Radiologists, R.A.'s or R.P.A.'s and R.T.'s currently licensed in Oregon are considered to have met the training requirements in (15)(l) of this rule.
(17) Fluoroscopic equipment operators who qualified to operate fluoroscopic x-ray equipment prior to April 11, 2005, will be considered as having met the training requirements in (15)(l) of this rule.
(18) 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.A's and R.P.A's may issue a preliminary report, however, the final report must be issued by their supervising radiologist.
(19) Written procedures for fluoroscopic x-ray equipment operators shall be available at the worksite and include:

(a) A list of all individuals who are permitted to operate fluoroscopic x-ray equipment at the facility;
(b) A list of the fluoroscopic x-ray equipment that each operator is qualified to operate;
(c) Written procedures regarding the set up and operation of each fluoroscopic x-ray machine registered to the facility;
(d) Written radiation safety procedures pertaining to the use and operation of fluoroscopy; and
(e) The name and title of the individual who is responsible for the direction of R.T.'s who operate fluoroscopic equipment.
(20) 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 OAR333-106-0005(8) of these rules using measurement protocol in compliance with OAR 333-106-0210 of these rules 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.
(21) Facilities that utilize fluoroscopy shall maintain a record of the cumulative fluoroscopic exposure time used for each examination. The record must indicate the patients name, the type of examination, the date of the examination, the fluoroscopists name, the fluoroscopic room in which the examination was done and the total cumulative fluoroscopic on time for each fluoroscopic examination and:
(a) No later than May 1, 2006, establish cumulative fluoroscopic on-time benchmarks for at least two (if applicable) of the most common types of fluoroscopic examinations performed at ~~their~~ the facility's site in each of the following categories:
(A) Routine procedures performed on adults;
(B) Routine procedures performed on children;
(C) Orthopedic procedures performed in surgery;
(D) Urologic procedures performed in surgery;
(E) Angiographic procedures performed;
(F) Interventional cardiac studies.
(b) Develop and perform periodic (not to exceed 12 month intervals) quality assurance studies to determine the status of each individual fluoroscopist's cumulative on-time in relation to the fluoroscopic benchmarks established for individual fluoroscopic examinations;
(c) Take appropriate action, when the established benchmarks are consistently exceeded. The Radiation Safety Committee (RSC) must review the results of the cumulative fluoroscopic on-time Quality Assurance Study and take corrective action regarding those individuals who have exceeded the benchmark/s established by the facility for a particular procedure more than ten percent of the total times the individual performed the procedure during the study period. Documentation of the RSC review, as well as any corrective action~~/s~~(s) taken, must be available for Agency review. Corrective action(s) should, at a minimum, include;
(A) Notification of the individual; and

(B) Recommendation that the individual undergo additional coaching, training, etc. in the safe use of fluoroscopic equipment in order to assist them in reducing their cumulative fluoroscopic on-times.
[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0050
Personnel Monitoring
All individuals who are associated with the operation of an X-ray system are subject to the requirements of OAR 333-120-0100 and 333-120-~~0140~~0210. In addition:
(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
(a) When an apron is worn, the monitoring device shall be worn at the collar outside of the apron;
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ (which are the gonads, the blood-forming organs, head and ~~truck~~ trunk or lens of the eye), shall be recorded in the reports required by OAR 333-120-0650(3). If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
Stat. Auth.: ORS 453.605 - 453.755
Stats. Implemented: ORS 453.605 – 453.775

333-106-0055
X-ray Operator Training
(1) The registrant shall assure that individuals who will be operating the x-ray equipment shall have adequate training in radiation safety. Adequate training in radiation safety means a minimum of 40 hours of didactic instruction for diagnostic medical x-ray equipment operators, 8 hours for Grenz ray x-ray equipment operators and 20 hours for veterinary x-ray equipment operators from an Agency approved training course covering the following subjects:
(a) Nature of x-rays;
(b) Interaction of x-rays with matter;
(c) Radiation units;
(d) Principles of the x-ray machine;
(e) Biological effects of x-ray;
(f) Principles of radiation protection;
(g) Low dose techniques;
(h) Applicable Federal and State radiation regulations including those portions of divisions 100, 101, 103, 106, 111 and 120 of chapter 333;
(i) Darkroom and film processing;
(j) Film critique.

NOTE: Subjects (1)(g), (1)(i) and (1)(j) are not required for Grenz ray x-ray equipment operator training.
(2) Dental x-ray operators who meet the following requirements are considered to have met the requirements in section (1) of this rule:
(a) Currently licensed by the Oregon Board of Dentistry as a Dentist or Dental Hygienist; or
(b) Is a Dental Assistant who is certified, by the Oregon Board of Dentistry, in radiologic proficiency; and
(c) Successfully completed didactic and clinical radiography training covering the subject areas outlined in section (1) of this rule; and
(d) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered by the Dental Assisting National Board, Inc.(DANB) and clinical radiography examination or other comparable requirements approved by the Oregon Board of Dentistry.
(3) Medical x-ray equipment operators not regulated by the Oregon Board of Radiologic Technology. In addition to the above, medical x-ray equipment operators using diagnostic radiographic equipment on human patients, and who are not regulated by the Oregon Board of Radiologic Technology must have 100 hours or more of instruction in radiologic technology including, but not limited to, anatomy physiology, patient positioning, exposure and technique. The instruction must be appropriate to the types of x-ray examinations that the individual will be performing; and
(a) Have 200 hours or more of x-ray laboratory instruction and practice in the actual use of an energized x-ray unit, setting techniques and practicing positioning of the appropriate diagnostic radiographic procedures that they intend to administer; and
(b) Must have completed the required radiation use and safety hours and a minimum of 50 hours in x-ray laboratory before x-raying a human patient.
(4) Radiation Use and Safety Instructor Qualifications. The training required in sections (1), (2) and (3) of this rule must be taught by an Agency approved Instructor. Approval will be based upon the following criteria:
(a) Medical use and safety instructor: An individual who is currently licensed as a Radiologic Technologist and approved as an education provider by the Oregon Board of Radiologic Technology.
(b) A dental radiation use and safety instructor is an individual who has:
(A) Passed the Radiation Health and Safety (RHS) or the Certified Dental Assistant (CDA) examination administered DANB; or
(B) Has been evaluated and approved as a qualified Dental radiation use and safety instructor by the Oregon Board of Dentistry; and
(C) Is currently licensed, by the Oregon Board of Dentistry as a dentist; or
(D) Is a dental hygienist; or
(E) Is a dental assistant certified in Radiologic proficiency and has a minimum of two years of experience in taking dental radiographs.
(c) A veterinarian radiation use and safety instructor is an individual who is:
(A) Currently credentialed with the Oregon Veterinary Medical Examining Board, or licensed as a Radiologic Technologist by the Oregon Board of Radiologic Technology; and

(B) Has completed training specific to veterinarian radiography, including restraining training; and
(C) Have a minimum of two years of experience in taking veterinary radiographs.
(d)(A) On a case by case basis, if an evaluation by the Agency reveals the individual has alternative qualifications that are substantially equivalent to the qualifications listed in sections (4)(a), (b) or (c) of this rule or is an individual who is qualified under OAR333-101-0230 as a Hospital Radiology Inspector; or
(B) The individual meets the requirements of a qualified expert as defined in OAR333-100-0005(80).
(5) In addition to the requirements in sections (2), (9), (10) and (13), of this rule dental x-ray equipment operator must also satisfy any requirements established by the Oregon Board of Dentistry.
(6) The operator shall be able to demonstrate competency in the safe use of the x-ray equipment and associated x-ray procedures.
(7) Any diagnostic medical x-ray operator is deemed to have adequate training to meet the requirements of section (1) of this rule if they meet any of the following:
(a) Holds a current license from the Oregon Board of Radiologic Technology; or
(b) Holds a current limited permit from the Oregon Board of Radiologic Technology; or
(c) Is a student in a two-year approved school of Radiologic Technology as defined in ORS 688.405 while practicing Radiologic Technology under the supervision of a radiologist who is currently licensed with the Oregon Medical Examiners Board or a radiologic technologist who is currently registered with the American Registry of Radiologic Technologists and licensed with the Oregon Board of Radiologic Technology; or
(d) Is a student in an Oregon Board of Radiologic Technology approved limited permit program under a Radiologic Technologist who is currently registered with the American Registry of Radiologic Technologists and licensed by the Oregon Board of Radiologic Technology.
(8) Dental radiology students in an approved Oregon Board of Dentistry dental radiology course are permitted to take dental radiographs on human patients during their clinical training, under the indirect supervision of a Dentist or Dental Hygienist currently licensed or a dental assistant who has been certified in radiologic proficiency, by the Oregon Board of Dentistry provided that:
(a) They are enrolled in an Oregon Board of Dentistry approved radiology course; or
(b) A student studying under an Oregon Board of Dentistry approved radiology instructor; and
(c) The student has written authorization, signed by their instructor, attesting that the student has successfully completed training in the subject areas in section (1) of this rule; and
(d) Demonstrated to the instructor that they are ready to take dental radiographs on human patients through;
(A) The use of mannequins under indirect supervision; or
(B) Taking dental radiographs of human patients while under the direct supervision of the instructor; and
(C) The written authorization is on the training program or Oregon Board of Dentistry approved instructor's letterhead, a copy of which is maintained at the site/s of their

clinical training and available for review by, DHS Office of State Public Health, inspection staff at the time of inspection.
(9) The students identified in section (8) of this rule are prohibited from taking radiographs on human patients without proper authorization from a practitioner of the healing arts who is currently licensed in Oregon, as required in OAR 333-106-0035 of these rules.
(10) The students identified in section (8) of this rule are considered to be in "student status" until they have successfully completed the clinical phase of their training. "Student status" shall not exceed a period of twelve (12) consecutive months.
(11) Radiation use and safety training programs approved prior to the May 1, 2005 will continue to be considered as meeting the requirements of section (1) of this rule provided they cover those portions of the Oregon Rules for the Control of Radiation indicated in section (1)(h) of this rule.
(12) X-ray operator training approved prior to May 1, 2005 will continue to be considered as having met the requirements of sections (1), (2) or (3) of this rule as applicable.
(13) Reciprocity. X-ray equipment operators who have received their radiation safety training outside of Oregon will be considered to have met the training requirements listed in sections (1) or (2) ~~as applicable~~ of this rule, if the Agency's or applicable Oregon Licensing Board's evaluation of their training or training and experience, reveals that they substantially meet the intent of sections (1) or (2) of this rule.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0101
Diagnostic X-ray Systems
Additional Requirements. In addition to other requirements of this division, all diagnostic x-ray systems shall meet the following requirements:
(1) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
(2) The state will attach an identification number to each x-ray control panel or an appropriate location:
(a) Identification numbers shall not be removed without written permission of the Agency;
(b) Identification numbers shall not be defaced.
(3) Mobile and portable x-ray systems shall meet the requirements of a stationary system when used for greater than seven consecutive days in the same location.
(4) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
(5) Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 mR (25.8 C/kg) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by

measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.
(6) Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 mR (0.516 C/kg) in one hour at 5 cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.
(7) Beam Quality:
(a) Half-Value Layer (HVL):
The HVL of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 4. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in Table 4, linear interpolation or extrapolation may be made; The referenced table is available on the Agency's website: http://www.oregon.gov/DHS/ph/rps/index.shtml
(A) The HVL required in section (7)(a) of this rule will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 5. The referenced table is available on the Agency's website: http://www.oregon.gov/DHS/ph/rps/index.shtml
(B) In addition to the requirements of section (5) of this rule, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum HVL not less than 1.5 mm aluminum (Al) equivalent filtration permanently installed in the useful beam;
(C) Beryllium window tubes shall have a minimum of 0.5 mm Al equivalent filtration permanently installed in the useful beam;
(D) For capacitor energy storage equipment, compliance with the requirements of section (5) of this rule shall be determined with the maximum quantity of charge per exposure;
(E) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials, which are always, present between the source and the patient.
(b) Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by ~~sub~~section (5)(a) of this rule is in the useful beam for the given kVp, which has been selected.
(8) Multiple Tubes. Where 2 or more radiographic tubes are controlled by one exposure switch, the tube or tubes, which have been selected, shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly, which has been selected.
(9) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.
(10) Technique Indicators:
(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors, which are set prior to the exposure, shall be indicated;

(b) The requirement of ~~sub~~section (10)(a) of this rule may be met by permanent marking on equipment having fixed technique factors.
(11) There shall be provided for each x-ray machine a means for determining the proper SID.
(12) X-ray film developing requirements. Compliance with this section is required of all healing arts registrants and is designed to ensure that patient and operator exposure is minimized and to produce optimum image quality and diagnostic information:
(a) Manual processing of films.
(A) The relationship between temperature of the developer and development time indicated in Table 6 or the manufacturer's recommendations must be used with standard developing chemistry. The referenced table is available on the Agency's website: http://www.oregon.gov/DHS/ph/rps/index.shtml
(B) Processing of film. All films shall be processed in such a fashion as to achieve adequate sensitometric performance. This criterion shall be adjudged to have been met if:
(i) Film manufacturer's published recommendations for time and temperature are followed; or
(ii) Each film is developed in accordance with the time-temperature chart (see section (12)(a) of this rule).
(C) Chemical-film processing control.
(i) Chemicals shall be mixed in accordance with the chemical manufacturer's recommendations;
(ii) Developer replenisher shall be periodically added to the developer tank based on the recommendations of the chemical or film manufacturer. Solution may be removed from the tank to permit the addition of an adequate volume of replenisher.
(D) All processing chemicals shall be completely replaced at least every two months or as indicated by the manufacturer.
(E) Devices shall be available which will:
(i) Give the actual temperature of the developer; and
(ii) Give an audible or visible signal indicating the termination of a preset development time (in minutes or seconds).
(b) Automatic film processing. Films shall be processed in such a manner that the degree of film development is the same as would be achieved by proper adherence to subsection (a) of this section (manual processing).
(c) Darkrooms. Darkrooms shall be constructed so that film being processed, handled, or stored will be exposed only to light which has passed through an appropriate safelight filter.
(d) Safelights shall be mounted in accordance with manufacturer's recommendations.
(e) Light bulbs used in safelights shall be the type and wattage recommended by the manufacturer.
(f) Safelight lenses shall be the type recommended for use by the film manufacturer.
(g) Rapid film processing. Special chemicals have been designed for use in Endodontics. These chemicals have special development requirements and do not permit as large of a margin of error in darkroom technique as do standard developing chemicals. Failure to precisely follow manufacturer's recommendations can easily lead to overexposure and underdevelopment. Darkroom procedures shall include:

(A) The manufacturer's time temperature development is crucial and shall be followed exactly;
(B) Caution: A timer capable of accurately measuring the short development times required shall be used;
(C) If rapid chemical processing is used for general radiography all applicable requirements of section (12) of this rule shall be followed.
(h) The department shall make such tests as may be necessary to determine compliance with this section.
[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0105
Information and Maintenance Record and Associated Information
(1) The registrant shall maintain the following information for each x-ray and automatic film processing system for inspection by the Agency:
(a) Model, serial numbers and manufacturer's user manuals for all x-ray systems and automatic film processors;
(b) Tube rating charts and cooling curves;
(c) Records of surveys, calibrations maintenance, and modification performed on the x-ray system(s) with names of persons who perform such services;
(d) A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the current use of areas adjacent to the room and an estimate of the extent of occupancy by individuals in such areas. In addition, the drawing shall include:
(A) The result of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
(B) The type and thickness of materials, or lead equivalency, of each protective barrier.
(e) A copy of all correspondence with this Agency regarding that x-ray system;
(f) Provisions in section (1) of this rule shall pertain to X-ray systems placed in service after the effective date of these rules.
(2) X-ray Log. Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed and the name of the x-ray operator. The x-ray log must have a cover page containing the printed names of all x-ray operators and a sample of their signed initials. The following facilities are exempt from ~~this~~these requirements:
(a) Dental facilities that maintain patient records showing the type and date of the examination and the operator's name;
(b) Industrial facilities doing industrial X-ray only;
(c) Veterinary facilities;
(d) Hospitals or clinics who employ only fully licensed X-ray operators;
(e) Doctors' offices or clinics with only 1 X-ray operator, or 1 X-ray exam;
(f) Academic, when not X-raying humans.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0110

Plan Review
When required by the Agency, and:
(1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes must be submitted to the Agency for review and approval. The required information is as set out in division 120.
(2) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.
(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in division 120.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0130
Design Requirements for an Operator's Booth
(1) Space Requirements when required by OAR 333-106-0110 of these rules:
(a) The operator shall be allotted not less than 7.5 square feet (0.697 m~~2~~^{2}) of unobstructed floor space in the booth;
(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m);
(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments;
(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.
(2) Structural Requirements:
(a) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high;
(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;
(c) Shielding shall be provided to meet the requirements of division 120 of these rules.
(3) X-ray Exposure Control Placement: The X-ray exposure control for the system shall be fixed within the booth and:
(a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table;
(b) Shall allow the operator to use the majority of the available viewing windows.
(4) Viewing System Requirements:
(a) Each booth shall have at least one viewing device which will:
(A) Be so placed that the operator can view the patient during any exposure; and
(B) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door

must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.
(b) When the viewing system is a window, the following requirements also apply:
(A) The viewing area shall be at least one square foot (0.0929 m2);
(B) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the X-ray system is at least 18 inches (0.457 m) from the edge of the booth;
(C) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.
(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;
(d) When the viewing system is by electronic means:
(A) The camera shall be so located as to accomplish the general requirements of subsection (4)(a) of this rule;
(B) There shall be an alternate viewing system as a backup for the primary system.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0201
Fluoroscopic X-ray Systems
All Fluoroscopic X-ray Systems Shall Meet the Following Requirements:
~~**Limitations of Useful Beam**~~
Limitations of Useful Beam
(1) Primary Barrier:
(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID;
(b) The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.
(2) Nonimage intensified types of fluoroscopes shall not be used.
(3) Image-Intensified Fluoroscopy and Spot Filming:
(a) For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. In addition:
(A) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square cm shall be provided with means for stepless adjustment of the X-ray field;
(B) All equipment with a fixed SID and a visible area of 300 square cm or less shall be provided with either stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of ~~five~~ 5 cm ~~centimeters~~ by 5 cm or less;
(C) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor; and

(D) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.
(b) Spot-film devices which are certified components shall meet the following additional requirements:
(A) Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
(B) It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 cm by 5 cm;
(C) The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and
(D) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
(c) If a means exists to override any of the automatic X-ray field size adjustments required in section (2) of this rule, that means:
(A) Shall be designed for use only in the event of system failure;
(B) Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
(C) Shall be clearly and durably labeled as follows:
"FOR X-RAY FIELD LIMITATION SYSTEM FAILURE"
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0210
Entrance Exposure Rates
(1) Fluoroscopic equipment manufactured before May 19, 1995 that is provided with Automatic Exposure Rate Control (AERC) shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 roentgens (R) (2.58 mC/kg) per minute, at a point where the center of the useful beam enters the patient, except;
(a) During the recording of fluoroscopic images; or;
(b) When optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of

activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.
(2) Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, except;
(a) During the recording of fluoroscopic images; or
~~(A)~~(b) When optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.
(3) Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment that is provided with both an AERC and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute in either mode at a point where the center of the useful beam enters the patient, except;
(a) During the recording of fluoroscopic images, or;
(b) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.
(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in sections 1, 2, and 3 of this rule.
(5) For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements will apply:
(a) Fluoroscopic equipment operable at any combination of tube potential and current that will result in an exposure rate in excess of 5 R (1.29 mC/kg) per minute at a point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of the technique factors may be provided.
(b) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 10 R (2.58 mC/kg) per minute at a point where the center of the useful beam enters the patient except;
(A) During the recording of fluoroscopic images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.
(B) When an optional high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 20 R per minute at a point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the

operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.
(6) Measuring compliance. Compliance with the requirements of this rule shall be determined as follows:
(a) Movable grids and compression devices shall be removed from the useful beam during the measurement;
(~~a~~b) If the source is below the table, exposure rate shall be measured 1 cm above the tabletop or cradle;
(~~b~~c) If the source is above the table, the exposure rate shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;
(~~c~~d) For a C-arm type of fluoroscope, the exposure rate shall be measured 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly;
(~~d~~e) For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 cm from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop ~~if~~ is moveable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the X-ray table.
(7) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirement set forth in section 5 of this rule.
(8) Periodic measurement of entrance exposure rate shall be performed as follows:
(a) Such measurement shall be made annually or after any maintenance of the system which might affect the exposure rate; and
(b) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in OAR 333-106-0105(1)(c) of these rules. The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results; and
(c) Personnel monitoring devices may be used to perform the measurements required by subsection (8)(a) of this rule, provided the measurements are made as described in subsection (8)(d) of this rule;
(d) Conditions of periodic measurement of entrance exposure rate are as follows:
(A) The measurement shall be made under the conditions that satisfy the requirements of section (6) of this rule; and
(B) The kVp shall be the kVp typical of clinical use of the X-ray system; and
(C) The X-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system or the worst case; and
(D) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the X-ray system.
NOTE: Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

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

333-106-0215
Barrier Transmitted Radiation Rate Limits
(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 mR (0.516 μC/kg) per hour at 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
(2) Measuring Compliance of Barrier Transmission:
(a) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm;
(b) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop;
(c) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm;
(d) Movable grids and compression devices shall be removed from the useful beam during the measurement;
(e) The attenuation block shall be positioned in the useful beam ~~ten~~ 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0230
Fluoroscopic Timer
(1) Means shall be provided to present the cumulative ~~on-time~~on time of the fluoroscopic tube.
(2) The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
(3) A signal audible to the fluoroscopist, or the appropriate operator, shall indicate the completion of any preset cumulative ~~on-time~~on time; or if no audible signal is provided, the exposure shall terminate.
Stat. Auth.: ORS 453.752 – 453.775
Stats. Implemented: ORS 453.752 – 453.775

333-106-0301
Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary Systems, or Computed Tomography(CT) X-ray Systems ~~Beam Limitation~~
Beam Limitation
(1) The useful beam shall be limited to the area of clinical interest.
(2) General Purpose Stationary and Mobile X-ray Systems:

(a) There shall be provided a means for stepless adjustment of the size of the X-ray field, where the adjustment of each dimension of the field is independent of the other;
(b) A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam;
(c) Evidence of compliance with subsections (2)(a) and (2)(b) of this rule shall be shown on each radiograph taken, either by imaging part of the collimator on the radiograph or by imaging collimator nubs or pointers;
(d) Beam-defining lights used for visually defining perimeters of the X-ray field shall have an illumination great enough to be visualized by the operator under ambient light conditions;
(e) The Agency may grant an exemption on noncertified X-ray systems to subsections (2)(a) and (2)(b) of this rule provided the registrant makes a written application for such exemption and in that application:
(A) Demonstrates it is impractical to comply with subsections (2)(a) and (2)(b) of this rule; and
(B) The purpose of subsections (2)(a) and (2)(b) of this rule will be met by other methods.
(3) Additional Requirements for Stationary General Purpose X-ray Systems. In addition to the requirements of section (2) of this rule, all stationary general purpose X-ray systems shall meet the following requirements:
(a) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within ~~2~~two percent of the SID, and to indicate the SID to within two percent;
(b) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
(c) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within ~~2~~two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
(4) X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within ~~2~~two percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
(5) Special Purpose X-ray Systems:
(a) Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than ~~2~~two

percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor;
(b) Means shall be provided to align the center of the X-ray field with the center of the image receptor to within ~~2~~two percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor;
(c) Subsections (5)(a) and (5)(b) of this rule may be met with a system that meets the requirements for a general purpose X-ray system as specified in section (2) of this rule or, when alignment means are also provided, may be met with either:
(A) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
(B) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0305
Radiation Exposure Control Devices
(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:
(a) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;
(b) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.
(2) X-Ray Exposure Control:
(a) An X-ray exposure control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for:
(A) Exposure of ~~1/2~~0.5 seconds or less; or
(B) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
(b) Each X-ray exposure control shall be located in such a way as to meet the following requirements:
(A) Stationary X-ray systems shall be required to have the X-ray exposure control permanently mounted in a protected area so that the operator is required to 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; and
(C) Mobile and portable X-ray systems which are:

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph (2)(b)(A) of this rule;
(ii) Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of subparagraph (2)(b)(C)(i) of this rule or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or
(iii) Used to make an exposure(s) of a patient at the use location shall meet the requirement of subparagraph (2)(b)(C)(i) or (ii) of this rule or be provided with a method of X-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.
(c) The X-ray control shall provide 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.
(3) Automatic Exposure Controls. When an automatic exposure control is provided:
(a) Indication shall be made on the control panel when this mode of operation is selected;
(b) If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
(c) The minimum exposure time for all equipment other than that specified in subsection (3)(b) of this rule shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;
(d) Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subsection (3)(d) of this rule, and manual resetting shall be required before further automatically timed exposures can be made.
(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (Tmax) minus the minimum exposure period (Tmin) when four timer tests are performed: (T)>/- 5 (Tmax - Tmin).
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0315
Exposure Reproducibility
The coefficient of variation of exposure shall not exceed 0.05~~10~~ 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 5 times the maximum exposure (Emax) minus the minimum exposure (Emin). E >/- 5 (Emax - Emin).
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0320

Radiation from Capacitor Energy Storage Equipment in Standby Status

Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of two milliroentgens (0.516 μC/kg) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

Stat. Auth.: ORS 453.605 - 453.77~~5~~5

Stats. Implemented: ORS 453.752 – 453.775

333-106-0325

Intraoral Dental Radiographic Systems

In addition to the provisions of OAR 333-106-0010 through 333-106-0101 of these rules, 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 of these rules. 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:

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

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

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

(a) ~~The beam size at an 18 cm source to image distance (SSD) shall be containable in a circle having a diameter of no larger than 7 cm~~ If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven centimeters; or

(b) ~~The beam size at an SSD of less than 18 cm must be containable in a circle having a diameter of no larger than 6 cm~~ If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six centimeters.

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

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

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

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

(d) Exposure termination.

(e) Timer Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure time (T) shall be greater than or equal to five times the minimum exposure time (T_{max}) minus the minimum exposure time (T_{min}) when four timer tests are performed: (T) >/- 5 (T_{max} – T_{min}).
(A) Means shall be provided to terminate the exposure at a preset, time interval, mAs, number of pulses, or radiation to the image receptor.
(B) An x-ray exposure control shall be incorporated into each system such that an exposure can be terminated by the operator at any time, except for exposures of ~~1/2~~0.5 seconds 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 ~~behind a secondary protective barrier in a protected area as defined in OAR 333-106-0005 of these rules and the operator shall remain in that protected area during the entire exposure~~: ~~and~~
(a) The exposure switch shall be able to be operated in a protected area, as defined in OAR 333-106-0005(78)(a)(b), 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 ~~1~~one week in the same location, i.e., a room or suite, shall meet the requirements of ~~paragraph~~subsections (4)-(a) and (4)(b) of this rule;
(B) Used for less than ~~1~~one week at the same location, i.e., 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 ~~(9)~~ feet (2.7 meters) from the tube housing assembly while making exposures; or
(iii) A full length protective apron ~~and thyroid collar~~, of not less than 0.25 millimeter lead equivalent for operator protection, when using a hand held dental intraoral x-ray machine.
(5) Exposure Reproducibility. ~~When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05 for any specific combination of technique factors.~~ The coefficient of variation shall not exceed 0.05~~10~~ when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five~~5~~ 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~~. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for exposure time.~~
(b) kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 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 subsections (2)(a) of this rule or its updated version;
(d) All patients shall be provided with a leaded lap apron during any X-ray exposure;
(e) Dental fluoroscopy without image intensification shall not be used;
(f) Pointed cones shall not be utilized unless specific authorization has been granted by the Agency.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0350
Definitions
In addition to the definitions provided in division 100 and 106 of these rules, the following definitions shall be applicable to this rule.
(1) "Computed Tomography Dose Index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan. This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.
(2) "Contrast Scale" means the change in the linear attenuation coefficient per CTN relative to water.
(3) "CS" (see Contrast scale).
(4) "CT Conditions of Operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in OAR 333-106-0005.
(5) "CTDI" (see Computed tomography dose index).
(6) "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.
(7) CTN (see CT number).
(8) CT Number means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.
(9) "Dose Profile" means the dose as a function of position along a line.
(10) "Elemental Area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also Picture element.)
(11) "Multiple Tomogram System" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.
(12) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.
(13) "Nominal Tomographic Section Thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.
(14) "Picture Element" means an elemental area of a tomogram.

(15) "Reference Plane" means a plane which is displaced from and parallel to the tomographic plane.
(16) "Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.
(17) "Scan Increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.
(18) "Scan Sequence" means a preselected set of ~~2~~two or more scans performed consecutively under preselected set of ~~2~~two or more scans performed consecutively under preselected CT conditions of operation.
(19) "Scan Time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.
(20) "Single Tomogram System" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.
(21) "Tomographic Plane" means that geometric plane which is identified as corresponding to the output tomogram.
(22) "Tomographic Section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0355
Requirements for Equipment
(1) Termination of Exposure:
(a) Means shall be provided to terminate the X-ray exposure automatically by either de-energizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function;
(b) A visible signal shall indicate when the X-ray exposure has been terminated through the means required by subsection (1)(a) of this rule;
(c) The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.
(2) Tomographic Plane Indication and Alignment:
(a) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane;
(b) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes;
(c) If a device using a light source is used to satisfy subsection (2)(a) or (b) of this rule, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-On and Shutter Status Indicators and Control Switches:
(a) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed;
(b) Each emergency button or switch shall be clearly labeled as to its function.
(4) Indication of CT Conditions of Operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operations at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
(5) Extraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by OAR 333-106-0101(5) of these rules.
(6) Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
(7) Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985:
(a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters;
(b) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible;
(c) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel;
(d) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0365
Surveys, Calibrations, Spot Checks, and Operating Procedures
(1) Surveys:
(a) All CT X-ray systems installed after December 1990 and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard;
(b) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Agency upon request.
(2) Radiation Calibrations:

(a) The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;
(b) The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output;
(c) The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years;
(d) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use:
(A) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 +- 0.01 grams per cubic cm or a reasonable substitute. The phantom(s) shall be at least 14 cm in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 cm for systems designed to image the head or for whole body scanners operated in the head scanning mode;
(B) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation along a line parallel to the axis of rotation 1.0 cm from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;
(C) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;
(D) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.
(3) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.
(4) Calibration shall meet the following requirements:
(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;
(b) The CTDI along the two axes specified in paragraph (2)(d)(B) of this rule shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 cm from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.
NOTE: For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.
(c) The spot checks specified in section (5) of this rule shall be made;

(d) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.
(5) Spot Checks:
(a) The spot check procedures shall be in writing and shall have been developed by a qualified expert;
(b) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thick-ness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material;
(c) Spot checks shall be included in the calibration required by section (2) of this rule and at time intervals and under system conditions specified by a qualified expert;
(d) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operations as are used to perform calibrations required by section (2) of this rule. The images shall be retained, until a new calibration is performed, in two forms as follows:
(A) Photographic copies of the images obtained from the image display device; and
(B) Images stored in digital form on a storage medium compatible with the CT X-ray system.
(e) Written records of the spot checks performed shall be maintained for inspection by the Agency.
(6) Operating Procedures:
(a) The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation;
(b) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:
(A) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;
(B) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variation for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
(C) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
(D) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.
(7) If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0370
Operator Requirements
(1) Computed Tomography (CT) X-ray systems shall be operated by individuals who:

(a) Are registered with the American Registry of Radiologic Technologists (A.R.R.T); and
(b) Have received additional CT system training; and
(c) Meet the clinical experience requirements for C.T. established by A.R.R.T.; and
(d) Are currently licensed by the Oregon Board of Radiologic Technology.
(2) Individuals who are registered with the A.R.R.T. and credentialed as an R.T.(R) and (CT) are considered to have met the CT training requirement in 333-106-0370(1) of this rule and clinical experience requirement in subsection (1)(a) of this rule.
(3) Those individuals who have met the requirements of section (1) of this rule prior to the effective date of this rule are considered to have met subsection (1)(a) of this rule.
(4) Technologists operating CT systems must do so under the direction of a radiologist.
(5) Positron Emission-Computed Tomography (PET/CT) or Single Photon Emission-Computed Tomography (SPECT/CT) systems shall be operated by:
(a) Any registered radiographer with the credential R.T. (R); or
(b) Registered radiation therapist with the credential R.T. (T); and
(c) Who are currently licensed by the Oregon Board of Radiologic Technology; or
(d) Registered certified nuclear medicine technologist with the credentials R.T. (N); or
(e) Certified Nuclear Medicine Technologist (CNMT) by the Nuclear Medicine Technologist Certification Board (NMTCB).
(6) The individuals mentioned in section (5) of this rule must also have successfully completed appropriate additional education and training and demonstrated competency in the use and operation of PET/CT or SPECT/CT systems.
(7) Appropriate additional training is considered training that covers the topic areas outlined in the PET/CT curriculum developed by the Multi-Organizational Curriculum Project Group sponsored by the American Society of Radiologic Technologists and the Society of Nuclear Medicine Technologists, or equivalent training approved by the Agency and:
(a) Includes the content specified in the PET/CT curriculum for the area(s) that the individual is not already trained or certified in; or
(b) Individuals meeting the requirements of section (5) of this rule and who have successfully completed training that the Agency has evaluated and judged to be substantially equivalent to that specified in subsection (7)(a) of this rule.
(8) R.T.(N) 's or CNMT's who have become certified in Computed Tomography through the American Registry of Radiologic Technologists are considered to have met the training requirements in section (5) of this rule.
(9) Technologists operating PET/CT or SPECT/CT systems must do so under the direction of an authorized user licensed to perform imaging and localization studies in accordance with OAR 333-116-0320 of these rules.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0601
Veterinary Medicine Radiographic Installations Additional Requirements
(1) Equipment:
(a) The protective tube housing shall be of the diagnostic type;

(b) Collimating devices shall be provided and used for collimating the useful beam to the area of clinical interest;
(c) All X-ray equipment sold (etc.) after October 1991 must be equipped with a variable adjustable collimator and beam-defining light that meets all of the requirements of OAR 333-106-0301(1), (2) and (3) of these rules;
(d) The total filtration permanently in the useful beam shall not be less than 0.5 mm Al equivalent for machines operating up to 50 KVp, 1.5 mm Al equivalent for machines operating between 50 and 70 kVp, and 2.5 mm Al equivalent for machines operating above 70 kVp;
(e) A device shall be provided to terminate the exposure after a preset time or exposure;
(f) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 12 feet (3.66 m) from the animal during all X-ray exposures.
(2) Structural Shielding: All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with division 120.
(3) Operating Procedures:
(a) ~~The operator~~ All individuals shall stand well away from the useful beam and the animal during radiographic exposures;
(b) No individual ~~other than the operator~~ shall be in the X-ray room while exposures are being made unless such individual's assistance is required;
(c) When an animal must be held in position during radiography, mechanical supporting or restraining devices ~~should~~ shall be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and that individual shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored with appropriate personnel monitoring devices.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0700
Mammography X-Ray Systems Definitions
In addition to the definitions provided in division 100 and 106 of these rules, the following definitions shall be applicable to the rules in this section.
(1) Air Kerma means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a given mass of air. The unit used to measure the quantity of kerma is the Gray (Gy). For x-rays with energies below 300 kiloelectronvolts (keV), 1Gy=100 rad and is equivalent to 114 (R) of exposure.
(2) FDA means the Food and Drug Administration.
(3) An Image receptor support surface means that portion of the image receptor support which is the x-ray input surface and is used to support the patient's breast during mammography.
(4) Interpreting physician means a licensed physician who interprets mammographic images and meets the qualifications of OAR 333-106-0750(2) of these rules.
(5) Lead Interpreting Physician means a physician who interprets mammographic images, meets the qualifications of OAR 333-106-0750(2) of these rules, and who has the general

responsibility for ensuring that the registrant's quality assurance program meets all applicable rules and regulations.
(6) Mammographic screening means the use of radiation to test women for the detection of diseases of the breast when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such tests for the purposes of diagnosis. Screening is considered as self-referral by asymptomatic women without physicians orders (see OAR 333-100-0020(5)(6) and 333-106-0035(3)).
(7) Mammography means radiography of the breast.
(8) Mammography equipment evaluation means an onsite assessment of a mammography unit/s or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable state and federal standards.
(9) Mammography unit/s means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum; An X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.
(10) Medical Physicist means a person trained in evaluating the performance of mammography equipment and quality assurance programs and meets the qualifications of OAR 333-106-0750(3) of these rules.
(11) MQSA means the Mammography Quality Standards Act of 1992.
(12) Phantom means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. (The "FDA accepted phantom" meets this requirement.)
(13) Quality Assurance is a comprehensive concept that comprises all of the management practices instituted by the registrant or the registrant's representative/s to ensure that:
(a) Every imaging procedure is necessary and appropriate to the clinical problem at hand;
(b) The images generated contain information critical to the solution of that problem;
(c) The recorded information is correctly interpreted and made available in a timely fashion to the patient's physician;
(d) The examination results in the lowest possible radiation exposure, cost, and inconvenience to the patient, consistent with ~~objective~~ subsection (13)(b) of this rule.
(14) Quality Assurance Program includes such facets as efficacy studies, continuing education, quality control, preventive maintenance, and calibration of equipment.
(15) Quality Control means a series of distinct technical procedures that ensure the production of a satisfactory product, e.g., a high quality screening or diagnostic image.
(16) Quality Control Technologist means an individual who is qualified under MQSA, and who is responsible for those quality assurance responsibilities not assigned to the Lead Interpreting Physician or to the Medical Physicist.
(17) Resting period means the period of time necessary to bleed out air that has been trapped between the radiographic film and intensifying screen during the loading process in the darkroom. This period of time is usually measured in minutes and determined by the individual manufacturer of the intensifying screen/mammography cassette combination.
(18) Standard Breast means a 4.2 cm thick compressed breast, consisting of 50 percent adipose, and 50 percent glandular tissue.

(19) Survey means an onsite physics consultation and evaluation of a registrant's mammography equipment, and quality assurance program performed by a medical physicist.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0720
Quality Assurance Program
(1) The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system. The quality assurance program shall include the testing required in section (5) of this rule, as well as the evaluation of the test results and corrective actions necessary to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement are as follows:
(a) The registrant shall identify in policy/procedure, by name, a Lead Interpreting Physician meeting the requirements of OAR 333-106-0750(2) ~~of these rules~~, whose responsibilities at a minimum must include:
(A) Ensuring that the registrant's quality assurance program meets all associated rules and regulations;
(B) Ensuring that an effective quality assurance program exists;
(C) Providing frequent feedback to mammography technologists regarding film quality and quality control procedures;
(D) Reviewing the Quality Control Technologist's test data at least every three months, or more if consistency has not been shown or problems are evident;
(E) Reviewing the Medical Physicist's annual survey report or equipment evaluation results.
(b) The registrant shall identify in policy/procedure, by name, and have the services of, a Medical Physicist who meets the requirements of OAR 333-106-0750(3) ~~of these rules~~. The Medical Physicist shall assist in overseeing the equipment quality assurance practices of the registrant. At a minimum, the Medical Physicist shall be responsible for the annual surveys, mammography equipment evaluations, and associated reports meeting all the requirements of MQSA.
(c) The registrant shall identify in policy/procedure, by name, a single qualified Quality Control Technologist meeting the requirements of OAR 333-106-0750(1) ~~of these rules~~, who shall be responsible for:
(A) Equipment performance monitoring functions;
(B) Analyzing the monitoring results to determine if there are problems requiring correction;
(C) Carrying out or arranging for the necessary corrective actions when results of quality control tests including those specified in section (5) of this rule, indicate the need; and
(D) The Quality Control Technologist may be assigned other tasks associated with the quality assurance program that are not assigned to the Lead Interpreting Physician or Medical Physicist. These additional tasks must be documented in written policy/procedure.
(2) Annual Survey. At intervals not to exceed 12-14 months, the registrant shall have a Medical Physicist meeting the requirements of OAR 333-106-0750(3) ~~of these rules~~

conduct a survey to evaluate the mammography equipment, and the effectiveness of the quality assurance program required in section (1) of this rule. Records of annual surveys shall be maintained for a minimum of ~~2~~two years, and shall be available on-site for agency review.
(3) Annual survey/or equipment evaluation corrective actions. Corrective action shall be completed within 30 working days of when the registrant received written or verbal notice of recommendations or failures on their annual survey/or equipment evaluation report, unless otherwise noted in these rules or a written request for extension has been submitted to and approved by the Agency;
(a) Correction of equipment related failures or recommendations shall be demonstrated by a repeat test using the same test methodology and documentation, or a test accepted as the equivalent by the Agency, that was used to initially identify the problem.
(b) When the results of a quality control test/s fail to meet applicable action limits defined in these rules, the appropriate action regarding the suspension or continuation of mammography as defined in these rules or in MQSA, shall be taken.
(4) Quality assurance records. The registrant shall ensure that;
(a) Records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, policies, previous inspection findings, and radiation protection are maintained until inspected by the agency.
(b) Quality control monitoring data and records, problems detected by the analysis of that data, corrective actions, and records of the Lead Interpreting Physician's periodic reviews of the Quality Control Technologist's monitoring data taken must be maintained for a minimum of two ~~2~~ years.
(5) Equipment quality control tests frequency. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed or replaced and performed thereafter at least as often as the frequency specified in Table 7. The referenced table is available on the Agency's website: http://www.oregon.gov/DHS/ph/rps/index.shtml
(6) Testing methods and action limits for quality control tests shall meet the most current requirements of MQSA, in addition to the following;
(7) Screen/film contact. Screen film contact tests shall be performed on all screens used clinically, using a 40-mesh test tool and 4four cm thick sheet of acrylic. Screens demonstrating one or more areas of poor contact that are greater than ~~1~~one cm in diameter, that are not eliminated by screen cleaning, and remain in the same location during subsequent tests, shall not be used for mammography. Screen/film contact shall be such that any areas of poor contact, regardless of size, shall not detract from image quality.
(8) Processor performance. A processor performance test shall be performed by sensitometric means and evaluated daily, after the solution temperature in the processor has reached proper temperature, and just prior to processing any clinical mammograms. The test shall be an assessment of the base plus fog, mid-density, density difference, and developer temperature.
(a) Sensitometers and densitometers used to evaluate processor performance shall be calibrated per the manufacturer's recommended calibration procedures for such devices. A record of the calibration shall be maintained until inspected by the Agency. Densitometers shall be checked against the instrument control strip at least monthly.

(b) The mid-density and density difference action limits must be within + 0.15 of the control operating level.
(c) The base plus fog (B+F) action limit must be within + 0.03 of the control operating level.
(d) If the mid-density and/or the density difference fall outside of the + 0.10 control limit but within the + 0.15 control limit for a period of ~~3~~three days (a trend), steps must be taken to determine the cause and correct the problem;
(e) If the mid-density and/or the density difference falls outside of the + 0.15 control limit, mammograms must not be processed through the processor until the cause of the problem is determined, corrected, and a repeat test is done demonstrating that the mid-density and/or density difference are within the + 0.15 control limit;
(f) Processor quality control graphs must be in the format of the registrant's accrediting body or equivalent, and indicate test date/s, mid-density and density difference action limits, base plus fog action limit, film brand, type and emulsion number in use, the date when chemistry changes occurred and corrective action(s) taken when limits are exceeded;
(g) Cross over records and calculations must be maintained until reviewed by the Agency during the annual inspection. New mid-density and/or density difference operating levels must be charted on a new graph page.
(h) Re-establishment of operating levels must be done in accordance with the accrediting body's protocol regarding the appropriateness of this procedure or at the specific direction of the facility's medical physicist.
(i) While re-establishing operating levels (~~5~~five day average), the facility must chart each day's results against it's old operating control levels. At the end of the five days, a new chart must be established, indicating the new calculated operating limits. During the ~~5~~five day average, the facility will not be cited for having exceeded the old processor operating levels; and
(j) When collecting data for the ~~5~~five day average, a phantom image test shall be conducted each day to verify the adequacy of image quality. Should the phantom image test exceed either the 0.20 background optical density limit or the + 0.05 density difference limit, mammography must be suspended until the cause of the problem is identified and corrected, and a repeat phantom image test is shown to be within limits.
(9) Primary/secondary barrier transmission evaluation must be conducted upon initial x-ray system installation and significant modification of the system or the facility.
(10) Image quality. The mammography system must be capable of producing an image of the phantom demonstrating the following;
(a) A minimum score of 4.0 fibers, 3.0 speck groups, and 3.0 masses (or the most current minimum score established by the accrediting body and accepted by the FDA).
(b) Background density action limits within + 0.20 of the control level;
(c) Density difference action limits within + 0.05 of the control level;
(d) Milliampere seconds (mAs) within + 15percent~~%~~ of the control level;
(e) Demonstrating a level of contrast sufficient enough to clearly help define fibril, speck, and mass edges.
(f) Without objectionable levels of image noise or quantum mottle that obscure the visualization of fibrils, specks, or masses.
(g) Demonstrating reasonably sharp fibril, and mass margins.

(h) With a minimum optical density (measured at the center of the phantom) of 1.20.
(i) Phantom image test records must be in the most current format of the registrant's accrediting body or the equivalent, and indicate the exposure mode, kVp, and photo-cell used for the test as well as remarks indicating the corrective action that was taken when limits were exceeded.
(j) When phantom image results do not meet the requirements defined in subsections (10)(a), (b), (c), (d), (e), (f), (g), or (h) of this rule, corrective action must occur, and a repeat phantom image test must be performed demonstrating compliance, before further mammography examinations are performed using the x-ray machine.
(11) Darkroom fog. Darkroom fog levels shall not exceed 0.05 in optical density difference when sensitized film is exposed to darkroom conditions with safelight on for ~~2~~two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen so that after processing, an optical density of at least 1.20 is achieved.
(a) If the darkroom fog optical density difference exceeds 0.05 but is less than 0.10, mammography may be continued until the problem is corrected.
(b) If the darkroom fog optical density difference exceeds 0.10, mammography must be curtailed until the problem is corrected and the density difference no longer exceeds 0.05.
(12) Repeat rate. Corrective actions shall be recorded and the results of these corrective actions shall be assessed if the reject rate exceeds five~~5~~ percent or changes by + 2 percent~~%~~ from the previously measured rate. The reject rate shall be based on repeated clinical images.
[ED. NOTE: Tables referenced are available from the agency.]
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0730
Additional Requirements
(1) Masks. Masks shall be provided on the view boxes to block extraneous light from the viewer's eye when the illuminated surface of the view box is larger than the area of clinical interest.
(2) Film processors utilized for mammography shall be:
(a) Used with x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.
(b) Use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.
(c) Be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.
(3) Instruments and devices. The following instruments and devices shall be available and properly maintained;
(a) FDA accepted image quality phantom;
(b) 21 step sensitometer;
(c) Densitometer.
(4) Image retention. Clinical images shall be retained for a minimum of five~~5~~ years or not less than 10 years if no additional mammograms of the patient are performed.

(5) Mobile Mammography. In addition to meeting the requirements of this section as well as OAR 333-106-0710, 333-106-0720, 333-106-0730, and 333-106-0750 of these rules, registrants shall ensure that for a mammography system that is used at more than one location:
(a) The film processor is operated in accordance with the requirements of OAR 333-106-0720 of these rules, and is located where the mammography examinations are performed (batch processing is prohibited).
(b) The following tests are conducted, evaluated and documented after every move and before any mammography examinations are conducted, in order to verify that the unit's performance continues to meet quality requirements:
(A) Phantom image;
(B) The measured radiation output or the data from the post exposure mAs display does not deviate by more than + 10 percent~~%~~ of the established operating level.
(6) Technique charts. Mammography technique charts shall posted in the vicinity of the mammography system's X-ray control. The technique chart shall indicate;
(a) Technique factors for 3, 3-5, 5-7, and > 7 cm compressed breast thicknesses for fatty, 50 percent fatty-50 percent dense, and dense breast tissue;
(b) The target/filter combination to be used;
(c) The kVp to be selected for the patient sizes and breast tissue compositions indicated in subsection (6)(a) of this rule, or if an auto-kVp mode is used, indicate the post kVp that is selected;
(d) The exposure mode to be used (i.e. auto-kVp, manual, etc.);
(e) The manual technique factors to be used for small, medium, and large sized breast tissue specimens, and Implanted breasts;
(f) The film/screen combination to be used;
(g) The date that the technique chart was last reviewed for accuracy and the name of the reviewer.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807

333-106-0750
Personnel Qualifications
(1) Operator qualifications. In order to use any mammography X-ray machine the operator of the mammography X-ray unit must have the following qualifications:
(a) Have a current license issued by the Oregon Board of Radiologic Technology; and
(b) Have prior to the effective date of these rules qualified as a radiologic technologist under the MQSA interim rules or completed 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not be limited to;
(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging patients with breast implants;
(B) The performance of 25 examinations under the direct supervision of an individual qualified under this section; and
(C) At least eight~~8~~ hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(D) Be currently registered and in good standing with the American Registry of Radiologic Technologist (ARRT); and
(E) Be certified in mammography by the ARRT or the equivalent; or
(F) Provide documented evidence that an ARRT mammography certification test is scheduled. Technologists meeting the requirements of subsections (1)(a) and paragraghs (1)(b)(A), (B), (C), and (D) of this rule may work under the supervision (supervision means that a fully qualified technologist is on-site and readily available to answer questions or assist) of a technologist, meeting all of the requirements of this rule, for up to one year while waiting to take the certification test.
(2) Interpreting Physician qualifications. All physicians interpreting mammograms shall meet MQSA qualifications and hold a current license to practice medicine in the State of Oregon.
(3) Medical Physicist qualifications. All Medical Physicists conducting surveys and equipment evaluations of mammography facilities and providing oversight of their quality assurance programs shall;
(a) Meet MQSA requirements; and
(b) Be currently licensed as a vendor by the agency.
Stat. Auth.: ORS 453.605 - 453.807
Stats. Implemented: ORS 453.605 - 453.807