**R313. Environmental Quality, Waste Management and Radiation Control, Radiation.**

**R313-28. Use of X-Rays in the Healing Arts.**

**R313-28-10. Purpose and Scope.**

(1) Rule R313-28 contains the requirements for the use of x-rays in the healing arts.

(2) Rule R313-28 is adopted pursuant to Subsections 19-3-104(4) and 19-3-104(7).

**R313-28-20. Definitions.**

As used in Rule R313-28, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Actual focal spot" refer to "Focal spot."

"Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper.

"Assembler" means individuals 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 an employee or agent if they assemble components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having appropriate dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic EXPOSURE control" means a device that automatically controls one or more technique factors to get, at a preselected location, a required quantity of radiation. Phototimer and ion chamber devices are included in this category.

"Barrier" refer to "Protective barrier."

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.

"Certified components" means components of x-ray systems that are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means an x-ray system that has one or more certified components.

"Changeable filters" means filters designed to be removed by the operator.

"Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a population of observations.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Control panel" means that part of the x-ray control where the switches, knobs, push buttons, and other hardware necessary for setting the technique factors are mounted.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" means computed tomography.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that house these components.

"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.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of part of the human body for recording or visualization for diagnostic purposes.

"Entrance EXPOSURE rate" means the EXPOSURE free in air per unit time at the point where the useful beam enters the patient.

"Equipment" refer to "X-ray equipment."

"Field emission equipment" means equipment that uses an x-ray tube where electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem where x-ray photons produce a fluoroscopic image. It includes equipment housing, electrical interlocks, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

"Focal spot" means the area on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and where the useful beam originates. Also referred to as "Actual focal spot."

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer or HVL" means the thickness of specified material that attenuates the beam of radiation to an extent that the EXPOSURE rate is reduced to one-half of its original value. In this definition, the contribution of scatter radiation, other than scatter radiation that might be present initially in the beam concerned, is considered to be excluded.

"Healing arts" means any system, treatment, operation, diagnosis, prescription, or practice for ascertaining cure, relief, palliation, adjustment, or correction of any health indications, human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

"Healing arts screening" means the use of x-ray equipment to examine individuals who are asymptomatic for the disease or condition that is the reason the screening is being performed and the use of x-rays are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to order x-ray tests for the diagnosis.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, for example, kVp times mA times seconds.

"HVL" refers to "half-value layer."

"Image intensifier" means a device installed in its housing that instantaneously converts an x-ray pattern into a light image of higher energy density.

"Image receptor" means a device, for example, a fluorescent screen radiographic film, solid state detector, or gaseous detector, that transforms incident x-ray photons to produce a visible image or stores the information in a form that can be made into a visible image. When means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak" refer to "Peak tube potential."

"kV" means kilovolts.

"kVp" refer to "Peak tube potential."

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(a) the useful beam; and

(b) radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly that 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 ten millicoulombs, ten milliampere seconds, 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 other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"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 where the illumination is one-fourth of the maximum in the intersection.

"mA" means tube current in milliamperes.

"mAs" means milliampere second or the product of the tube current in milliamperes and the time of exposure in seconds.

"Mammography imaging medical physicist" means an individual who conducts mammography surveys of mammography facilities.

"Mammography survey" means an evaluation of x-ray imaging equipment and oversight of a mammography facility's quality control program.

"Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

"Multiple scan average dose" means the average dose at the center of a series of scans, specified at the center of the axis of rotation of a CT x-ray system.

"New installation" means change, modification, or relocation of new or existing shielding or equipment.

"Operator of diagnostic x-ray equipment" means either the individual responsible for insuring that the appropriate technique factors are set on the x-ray equipment or the individual who makes the radiation exposure.

"Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

"PBL" refer to "Positive beam limitation."

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

"PID" refers to "Position indicating device."

"Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

"Position indicating device (PID)" means a device, on dental x-ray equipment that shows the beam position and establishes a definite source-surface, skin, distance. The device may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without the adjustment.

"Primary beam scatter" means scattered radiation that has been deviated in direction or energy by materials irradiated by the primary beam.

"Primary protective barrier" refer to "Protective barrier."

"Protective apron" means an apron made of radiation absorbing materials, used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material used to reduce radiation exposure.

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

(b) "Secondary protective barrier" means the material that attenuates stray radiation.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and for confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor that the image is created directly or indirectly on by an x-ray pattern and results in a permanent record.

"Rating" means the operating limits of an x-ray system or subsystem as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons.

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"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.

"Scan increment" means the amount of relative displacement of the patient with respect to the computer tomographic x-ray system between successive scans measured along the direction of the displacement.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction, energy, or both direction and energy. Also refer to "Primary Beam Scatter."

"Shutter" means a device attached to the tube housing assembly that can intercept the entire cross sectional area of the useful beam and that has a lead equivalency at least that of the tube housing assembly.

"SID" refer to "Source-image receptor distance."

"Source" means the focal spot of the x-ray tube.

"Source to image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Special purpose x-ray system" means a system that is designed for irradiation of specific body parts.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Spot film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor, including a device intended to hold a cassette over the input end of an image intensifier to make a radiograph.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

(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 other equipment, peak tube potential in kV and either;

(i) the tube current in mA and exposure time in seconds; or

(ii) the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements if they are contained within the tube housing.

"Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

"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 switch or timer is activated.

"Visible area" means that portion of the input surface of the image receptor where incident x-ray photons are producing a visible image.

"X-ray exposure control" means a device, switch, button, or other similar means that an operator uses to initiate or terminate the radiation exposure. The x-ray exposure control may include associated equipment, for example, timers and back-up timers.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. See definitions for "Mobile x-ray equipment," "Portable x-ray equipment," and "Stationary x-ray equipment."

"X-ray field" means that area of the intersection of the useful beam and one of the sets of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points where the EXPOSURE rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that 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 high-voltage switches, electrical protective devices, and other appropriate elements.

"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 that function with the system are considered integral parts of the system.

"X-ray tube" means an electron tube that is designed to be used primarily for the production of x-rays.

**R313-28-31. General and Administrative Requirements.**

(1) A person may not make, sell, lease, transfer, lend, or install x-ray equipment or the accessories used in connection with x-ray equipment unless the accessories and equipment, if properly placed in operation and properly used, will meet the applicable requirements of Title R313.

(a) X-ray equipment shall be FDA approved for use in the United States and shall be certified in accordance with 21 CFR 1010.2 and identified in accordance with 21 CFR 1010.3.

(2) The registrant shall be responsible for directing the operation of the x-ray machines that are under the registrant's administrative control. The registrant or registrant's agent shall assure that the requirements of Subsections R313-28-31(2)(a) through R313-28-31(2)(i) are met in the operation of the x-ray machines.

(a) If directed by the director an x-ray machine that does not meet the requirements of Rule R313-28 may not be operated for diagnostic purposes.

(b) Individuals who will be operating the x-ray equipment shall be instructed in the registrant's written radiation safety program and be qualified in the safe use of the equipment. Required operator qualifications are listed in Section R313-28-350.

(c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding and restrictions of the operating technique required for the safe operation of the x-ray systems. Individuals who operate x-ray systems shall be responsible for complying with the applicable requirements of Title R313.

(d) Except for individuals who cannot be moved out of the room and the patient being examined, only the staff and ancillary personnel or other individuals needed for the medical procedure or training shall be present in the room during the radiographic exposure and shall be positioned as follows:

(i) individuals other than the patient shall be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 mm lead equivalent material;

(ii) the x-ray operator, other staff, ancillary personnel, and other individuals needed for the medical procedure shall be protected from primary beam scatter by protective aprons or barriers unless it can be shown that by virtue of distances used EXPOSURE levels are reduced to the limits specified in Section R313-15-201; and

(iii) patients who are not being examined and cannot be removed from the room shall be protected from the primary beam scatter by whole body protective barriers of not less than 0.25 mm lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and nearest edge of the image receptor.

(e) For patients who have not passed reproductive age, gonad shielding of not less than 0.5 mm lead equivalent material may be used during radiographic procedures if the gonads are in the useful beam, except for cases when this would interfere with the diagnostic procedure.

(f) Individuals shall be exposed to the useful beam for healing arts purposes only if the exposure has been specifically ordered and authorized by a licensed practitioner of the healing arts after a medical consultation. Deliberate exposures for the purposes listed in Subsections R313-28-31(2)(f)(i) and R313-28-31(2)(f)(ii) are prohibited:

(i) exposure of an individual for training, demonstration, or other non-healing arts purposes except for low dose, whole body scanners used for security purposes in correctional facilities; and

(ii) exposure of an individual for healing arts screening except as authorized by Subsection R313-28-31(2)(i).

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

(i) mechanical holding devices shall be used if the technique permits. The written procedures required by Subsection R313-28-31(2)(c) shall list individual projections where mechanical holding devices can be utilized;

(ii) written safety procedures as required by Subsection R313-28-31(2)(c) shall state the requirements for selecting an individual to hold patients or films and the procedure that individual shall follow;

(iii) the individual holding patients or films during radiographic examinations shall be instructed in personal radiation safety and protected as required by Subsection R313-28-31(2)(d)(i);

(iv) Individuals may not be used routinely to hold film or patients;

(v) In those cases when the patient must hold the film, except during intraoral examinations, portions of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material; and

(vi) Facilities shall have protective aprons and gloves available in sufficient numbers to provide protection to personnel who are involved with x-ray operations and who are otherwise not shielded.

(h) Personnel monitoring. Individuals who are associated with the operation of an x-ray system are subject to the applicable requirements of Rule R313-15.

(i) Healing arts screening. A person proposing to conduct a healing arts screening program may not initiate the program without first receiving approval from the director. When requesting approval that person shall submit the information outlined in Section R313-28-400. If information submitted becomes invalid or outdated the director shall be notified immediately.

(3) Maintenance of records and information. The registrant shall maintain at least the information listed in Subsections R313-28-31(3)(a) through R313-28-31(3)(c) for each x-ray machine:

(a) model numbers of major components;

(b) record of surveys or calculations to demonstrate compliance with Section R313-15-302, calibration, maintenance, and modifications performed on the x-ray machine; and

(c) a shielding design report for the x-ray suite that states assumed values for workload and use factors and includes a drawing of surrounding areas showing assumed values for occupancy factors.

(4) X-ray records. Facilities shall maintain an x-ray record containing the patient's name, the types of examinations, and the dates the examinations were performed. If the patient or film must be provided with human auxiliary support the name of the human holder shall be recorded. The registrant shall keep these records for three years after the record is made.

(5) Portable or mobile equipment shall be used only for examinations if it is impractical to transfer the patient to a stationary radiographic installation. Mobile equipment that is used in a room that was constructed in accordance with a shielding design in accordance with Sections R313-28-32 and R313-28-200 and is not moved from room to room is exempt from this requirement.

(6) Hand-held medical x-ray systems. X-ray equipment designed to be hand-held shall comply with Section R313-28-31, excluding Subsection R313-28-31(5), and Section R313-28-52, excluding Subsections R313-28-52(8)(b)(i) and R313-28-52(8)(b)(ii).

(a) When operating hand-held equipment if it is not possible for the operator to remain at least six feet from the x-ray machine during x-ray exposure protective aprons of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso and gonads from backscatter radiation.

(b) In addition to the dose limits in Section R313-15-301, operators of hand-held x-ray equipment shall ensure that members of the public that may be exposed to scatter radiation or primary beam transmission from the hand-held device are not exposed above two milliroentgen per hour.

(i) Operators will ensure that members of the public likely to be exposed to greater than two milliroentgen per hour will be provided protective aprons of at least 0.5 millimeter lead equivalence or are moved to a distance where the exposure rate to the individual is below two milliroentgen per hour.

(c) In addition to the requirements of Subsection R313-28-350(1), each operator of hand-held x-ray equipment shall complete the training program supplied by the manufacturer before using the x-ray unit. Records of training shall be maintained on file for examination by an authorized representative of the director.

(7) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(a) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens may not be used for routine diagnostic radiological imaging, with the exception of standard film packets for intraoral use in dental radiography. If the requirements of Subsection R313-28-31(6)(a) cannot be met an exemption may be requested pursuant to Section R313-12-55.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(c) X-ray systems, other than fluoroscopic, computed tomography, dental, or veterinary units, may not be utilized in procedures if the source to patient distance is less than 30 centimeters.

**R313-28-32. Plan Review.**

(1) Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation shall be submitted to a Qualified Expert for review. The required information is denoted in R313-28-200 and R313-28-450.

(2) A copy of the Qualified Expert's conclusions regarding shielding specifications must be submitted to the Director within 14 working days.

(3) The Director may require additional modifications should a subsequent analysis of operating conditions, for example, a change in workload or use and occupancy factors, indicate the possibility of an individual receiving a dose in excess of the limits prescribed in R313-15.

**R313-28-35. General Requirements for Diagnostic X-Ray Systems.**

In addition to other requirements of Rule R313-28, each diagnostic x-ray system shall meet the requirements in Section R313-28-35.

(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) Battery charge indicator. On battery powered generators visual means shall be provided on the control panel to show whether the battery is in a state of charge adequate for proper operation.

(3) 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 may not exceed 25.8 uC/kg, 100 milliroentgens, in one hour if the x-ray tube is operated at its leakage technique factors.

(4) Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly may not exceed 0.516 uC/kg, two milliroentgens, in one hour at five centimeters from accessible surfaces of the component if it is operated in an assembled x-ray system under the conditions that it was designed to operate under. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam quality.

(a) The half-value layer of the useful beam for a given x-ray tube potential may not be less than the values shown in Section R313-28-35, Table 1. If it is necessary to determine the half-value layer at an x-ray tube potential that is not listed in Table 1, linear interpolation or extrapolation may be made.

|  |  |  |  |
| --- | --- | --- | --- |
| Table 1 | | | |
| Design Operating Range (Kilovolts Peak) | Measured Potential (Kilovolts Peak) | Dental Intra-Oral Manufactured Before August 1, 1974 and On or Before December 1, 1980 | All Other Diagnostic X-Ray Systems |
| Below 51 | 30 | (use prohibited) | 0.3 |
|  | 40 | (use prohibited) | 0.4 |
|  | 50 | 1.5 | 0.5 |
|  | 51 | 1.5 | 1.2 |
|  | 60 | 1.5 | 1.3 |
|  | 70 | 1.5 | 1.5 |
| Above 70 | 71 | 2.1 | 2.1 |
|  | 80 | 2.3 | 2.3 |
|  | 90 | 2.5 | 2.5 |
|  | 100 | 2.7 | 2.7 |
|  | 110 | 3.0 | 3.0 |
|  | 120 | 3.2 | 3.2 |
|  | 130 | 3.5 | 3.5 |
|  | 140 | 3.8 | 3.8 |
|  | 150 | 4.1 | 4.1 |

(b) For capacitor discharge equipment compliance with the requirements of Subsection R313-28-35(5)(a) shall be determined with the system fully charged and a setting of 10 mAs for exposures.

(c) The required minimal half-value layer of the useful beam shall include the filtration contributed by materials that are permanently present between the focal spot of the tube and the patient.

(d) Filtration control. For x-ray systems that have variable kVp and variable filtration for the useful beam a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by Subsection R313-28-35(5)(a) is in the useful beam for the given kVp that has been selected.

(6) Multiple tubes. If two or more radiographic tubes are controlled by one exposure switch the tube or tubes that have been selected shall be clearly shown before initiation of the exposure. For equipment manufactured after August 1, 1974, indications shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(7) Mechanical support of tube head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement during exposure is a designed function of the x-ray system.

(8) Technique indicators.

(a) The technique factors to be used during an exposure shall be shown before the exposure begins, except when automatic EXPOSURE controls are used, in that case the technique factors that are set before the exposure shall be indicated.

(b) On equipment having fixed technique factors the requirements in Subsection R313-28-35(8)(a) may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) Maintaining compliance. Diagnostic x-ray systems and their associated components certified pursuant to the provisions of 21 CFR Part 1020 (2006) shall be maintained in compliance with applicable requirements of that standard.

(10) Locks. Each position locking, holding, and centering device on x-ray system components and systems shall function as intended.

(11) X-ray systems that have been granted a variance by the Director, Center for Devices and Radiological Health, Food and Drug Administration (Director), from the performance standards for ionizing radiation emitting products in accordance with 21 CFR 1010.4 (2006) shall be accepted as satisfying the requirements in Rule R313-28 that correspond to the variance granted by the Director. The registrant shall insure that labeling pursuant to 21 CFR 1010.5(f) (2006) remains legible and visible on the x-ray system.

**R313-28-40. Fluoroscopic X-Ray Systems.**

All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:

(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 SIDs for which the unit was designed.

(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) Fluoroscopic beam limitation.

(a) For certified fluoroscopic systems with or without a spot film device 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.

(b) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully open, during fluoroscopy or spot filming, shall be no larger than the largest image receptor size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

(c) For uncertified fluoroscopic systems without a spot film device, the requirements of R313-28-40(1) apply.

(d) Other requirements for fluoroscopic beam limitation:

(i) 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 or visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

(ii) equipment with a fixed SID and a visible area of 300 square centimeters 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 centimeters or less;

(iii) if provided, stepless adjustment shall at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

(iv) 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

(v) for non-circular x-ray fields used with circular image receptors, 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.

(3) Spot-film beam limitation. Spot-film devices shall meet the following 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. Adjustments 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) neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent of the SID;

(c) 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, five by five centimeters;

(d) 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

(e) 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.

(4) Override. If a means exists to override the automatic x-ray field size adjustments required in R313-28-40(2) and (3), 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.

(5) Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure immediately, but means may be provided to permit completion of a single exposure of the series in process.

(6) Entrance EXPOSURE rate allowable limits.

(a) For fluoroscopic equipment manufactured before May 19, 1995, the following requirements apply:

(i) fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the 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.

(ii) fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at combinations of tube potential and current which will result in a EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(A) during recording of fluoroscopic images, or

(B) when an 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.

(iii) fluoroscopic equipment which is provided with both automatic exposure rate control and a manual mode shall not be operable at combinations of tube potential and current that will result in an exposure rate of 2.58 mC/kg (ten roentgens) per minute in either mode at the point where the center of the useful beam enters the patient except:

(A) during recording of fluoroscopic images, or

(B) when an optional high level control is provided. When so provided, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 1.29 mC/kg (five roentgens) per minute at the 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.

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

(i) fluoroscopic equipment operable at combinations of tube potential and current which will result in an EXPOSURE rate greater than 1.29 mC/kg (five roentgens) per minute at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control. Provision for manual selection of technique factors may be provided.

(ii) fluoroscopic equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 2.58 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient except:

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

(B) when an optional high level control is activated. When the high level control is activated, the equipment shall not be operable at combinations of tube potential and current which will result in an EXPOSURE rate in excess of 5.16 mC/kg (20 roentgens) per minute at the 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.

(c) Compliance with the requirements of R313-28-40(6) shall be determined as follows:

(i) if the source is below the x-ray table, the EXPOSURE rate shall be measured one centimeter above the tabletop or cradle;

(ii) if the source is above the x-ray table, the EXPOSURE rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

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

(iv) for a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters 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 close as possible to the point of measurement. If the tabletop is movable, it shall be positioned as close as possible to the lateral x-ray source with the end of the beam-limiting device or spacer no closer than 15 centimeters to the x-ray table.

(d) Fluoroscopic radiation therapy simulation systems are exempt from the requirements of R313-28-40(6).

(7) Measurement of entrance EXPOSURE rates shall be performed for both maximum and typical values as follows:

(a) measurements shall be made annually or after maintenance of the system which might affect the EXPOSURE rate;

(b) results of these measurements shall be posted where the fluoroscopist may have ready access to the results while using the fluoroscope and in the record required in R313-28-31(3)(b). The measurement results shall be stated in roentgens per minute and include the machine settings used in determining results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results;

(c) conditions of the annual measurement of maximum entrance EXPOSURE rate shall be performed as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28-40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance EXPOSURE rate; and

(iii) x-ray systems that incorporate automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system; and

(d) conditions of the annual measurement of typical entrance EXPOSURE rate are as follows:

(i) the measurement shall be made under the conditions that satisfy the requirements of R313-28-40(6)(c);

(ii) the kVp, mA, and other selectable parameters shall be those settings typical of clinical use of the x-ray system; and

(iii) the x-ray system that incorporates automatic EXPOSURE rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and kilovoltage typical of the use of the x-ray system.

(8) Barrier transmitted radiation rate limits.

(a) 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 0.516 uC/kg (two milliroentgens) per hour at ten centimeters from accessible surfaces of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance EXPOSURE rate.

(b) Measuring compliance of barrier transmission.

(i) 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 centimeters with no linear dimension greater than 20 centimeters.

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

(iii) 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 centimeters.

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

(9) Indication of potential and current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.

(10) Source-skin distance. The source to skin distance shall not be less than:

(a) 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(b) 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(c) 30 centimeters on all mobile fluoroscopes; or

(d) 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

(11) Fluoroscopic timer.

(a) Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(b) A signal audible to the fluoroscopist shall indicate the completion of a preset cumulative on-time. The signal shall continue to sound while x-rays are produced until the timing device is reset.

(12) Control of scatter radiation.

(a) The tables of fluoroscopic assemblies when combined with normal operating procedures shall provide protection from scatter radiation so that unprotected parts of a staff or ancillary individual's body shall not be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

(b) Equipment configuration when combined with procedures shall not allow portions of a staff member's or ancillary person's body, except the extremities, to be exposed to unattenuated scattered radiation emanating from above the tabletop unless:

(i) the radiation has passed through not less than 0.25 mm lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self supporting curtains, in addition to the lead equivalency provided by the protective apron referred to in R313-28-31(2)(d),

(ii) that individual is at least 120 centimeters from the center of the useful beam, or

(iii) it is not feasible to attach shielding to special procedures equipment and personnel are wearing protective aprons.

(13) Spot film exposure reproducibility. Fluoroscopic systems equipped with radiographic spot film mode shall meet the exposure reproducibility requirements of R313-28-54.

(14) Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements R313-28-40(1), (8), and (11) provided that:

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

(b) the systems which do not meet the requirements of R313-28-40(11) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require, in these cases, that the timer be reset between examinations.

**R313-28-51. Radiographic Systems Other than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Beam Limitation.**

The useful beam shall be limited to the area of clinical interest and show evidence of collimation. This shall be deemed to have been met if a positive beam limiting device meeting the manufacturer's specifications or the requirements of R313-28-300 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, for example, projections of the shutters of the collimator, cone cutting at the corners or a border at the film's edge.

(1) General purpose stationary and mobile x-ray systems.

(a) Only x-ray systems provided with a means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

(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) The Board may grant an exemption on non-certified x-ray systems to R313-28-51(1)(a) and (b) provided the registrant makes a written application for the exemption and in that application:

(i) demonstrates it is impractical to comply with R313-28-51(1)(a) and (b); and

(ii) demonstrates the purpose of R313-28-51(1)(a) and (b) will be met by other methods.

(2) In addition to the requirements of R313-28-51(1) above, stationary general purpose x-ray systems, both certified and non-certified shall meet the following requirements:

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

(b) the beam-limiting device shall numerically indicate 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 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 of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.

(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges of the image receptor.

(4) 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 the x-ray field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(b) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond the edges 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) R313-28-51(4)(a) and R313-28-51(4)(b) may be met with a system that meets the requirements for a general purpose x-ray system as specified in R313-28-51(1) or, when alignment means are also provided, may be met with either;

(i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirements for the combination of image receptor sizes and SID's for which the unit is designed with the beam limiting device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for the combinations of image receptor sizes and SID's for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which the aperture is designed and shall indicate which aperture is in position for use.

**R313-28-52. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography -- Radiation Exposure Control Devices.**

(1) Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, for example, the depression of a switch. Radiation exposure shall not be initiated without a deliberate action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure termination. 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. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(3) Manual Exposure Control: An x-ray control shall be incorporated into x-ray systems so that an exposure can be terminated at times except for:

(a) exposure of one-half second or less; or

(b) during serial radiography when means shall be provided to permit completion of a single exposure of the series in process.

(4) Automatic EXPOSURE controls, phototimers. When automatic EXPOSURE control is provided:

(a) indication shall be made on the control panel when this mode of operation is selected;

(b) when the x-ray tube potential is equal to or greater than 51 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than the interval equivalent to two pulses; and

(c) the minimum exposure time for all equipment other than that specified in R313-28-52(4)(b) shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater.

(5) 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.

(6) Exposure Duration, Timer, Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location. The x-ray exposure control shall be placed so that the operator can view the patient while making the exposure.

(8) Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure switch permanently mounted in a protected area.

(b) Mobile and portable x-ray systems which are:

(i) used continuously for greater than one week at the same location, one room or suite, shall meet the requirements of R313-28-52(8)(a); or

(ii) used for less than one week at one location, one room, or suite shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

**R313-28-53. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Source-to-Skin or Receptor Distance.**

Mobile or portable radiographic systems shall be provided with a means to limit the source-to-skin distance to 30 or more centimeters.

**R313-28-54. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Exposure Reproducibility.**

When technique factors, including control panel selections associated with automatic exposure control systems, are held constant the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

**R313-28-55. Radiographic Systems - Standby Radiation From Capacitor Discharge Equipment.**

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

**R313-28-56. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- Accuracy.**

Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and ten percent of the indicated value for times greater than 50 milliseconds.

**R313-28-57. Radiographic Systems Other Than Fluoroscopic, or Dental Intraoral Systems -- mA/mAs Linearity.**

The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 percent to 100 percent of the maximum rated potentials.

(1) Equipment having independent selection of x-ray tube current, mA. Where the tube current is continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive tube current settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(2) Equipment having a combined x-ray tube current-exposure time product, mAs, selector, but not a separate tube current, mA, selector. Where the tube current is continuous, the average ratios of exposure to the indicated milliampere-seconds product, C/kg/mAs or mR/mAs, obtained at two consecutive milliampere-seconds settings or at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

**R313-28-80. Intraoral Dental Radiographic Systems.**

In addition to the provisions of R313-28-31, R313-28-32 and R313-28-35, the requirements of this section apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in R313-28-51, R313-28-52 and R313-28-53. Intraoral dental radiographic systems used must meet the requirements of R313-28-80.

(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 centimeters if operable above 50 kilovolts peak, or

(b) 10 centimeters if not operable above 50 kilovolts peak.

(2) Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field so that:

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

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

(3) Exposure Initiation.

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

(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.

(4) Exposure Termination.

(a) 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.

(b) An x-ray exposure control shall be incorporated into x-ray systems so that an exposure of more than 0.5 seconds can be terminated immediately by the operator.

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

(5) Exposure Indication. Means shall be provided for visual indication, observable 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.

(6) Timer Linearity. For systems having independent selection of exposure time settings, the average ratio of exposure to the indicated milliampere-seconds product obtained at two consecutive timer settings or at two settings not differing by more than a factor of two shall not differ by more than 0.10 times their sum.

(7) Exposure Control Location and Operator Protection.

(a) Stationary x-ray systems shall be required to have the x-ray exposure control mounted in a protected area or a means to allow the operator to be at least 2.7 meters (9.0 feet) from the tube housing assembly while making exposures; and

(b) Mobile and portable x-ray systems which are:

(i) used for greater than one week in the same location, for example, a room or suite, shall meet the requirements of R313-28-80(7)(a); or

(ii) used for less than one week in the same location shall be provided with either a protective barrier at least two meters high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

(8) Exposure Reproducibility. When all technique factors are held constant, the coefficient of variation of exposure shall not exceed 0.05 for certified x-ray systems or 0.10 for non-certified x-ray systems. This requirement applies to clinically used techniques.

(9) mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for fixed x-ray tube potentials within the range of 40 to 100 percent of the maximum rated potentials.

(a) For equipment having independent selection of x-ray tube current, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive tube current settings or, when the tube current selection is continuous, two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(b) For equipment having a combined x-ray tube current-exposure time product selector but not a separate tube current selector, the average ratios of exposure to the indicated milliampere-seconds product obtained at two consecutive mAs selector settings, or when the mAs selector provides continuous selection, at two settings differing by no more than a factor of two shall not differ by more than 0.10 times their sum.

(10) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed ten percent of the indicated value.

(11) Administrative Controls.

(a) Patient and film holding devices shall be used when the technique permits and holding is required.

(b) The x-ray tube housing and the position indicating device shall not be hand-held during an exposure.

(c) The x-ray system shall be operated so that the useful beam at the patient's skin does not exceed the requirements of R313-28-80(2).

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

(12) Hand-held Portable Dental X-ray Systems.

(a) X-ray equipment designed to be hand-held shall comply with Section R313-28-31, excluding Subsection R313-28-31(5), and with Section R313-28-80, excluding Subsections R313-28-80(7)(b) and R313-28-80(11)(b).

(b) Protective shielding of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso, hands, face, and gonads from backscatter radiation. If the protective shielding is a backscatter shield attached to the x-ray unit, the shield shall be positioned as close to the patient as possible and the operator shall take care to remain in a protective position.

(c) Portable radiation machines designed to be hand-held are exempt from Subsection R313-28-35(7). The portable radiation machines shall be held by the tube housing support or handle and shall be used in accordance with the manufacturer's operating procedures.

(d) In addition to the requirements of Subsection R313-28-350(1), each operator shall complete the training program supplied by the manufacturer prior to using the x-ray unit. Records of training shall be maintained on file for examination by an authorized representative of the Director.

**R313-28-120. Mammography X-Ray Systems - Equipment Design and Performance Standards.**

Only x-ray equipment meeting the following standards shall be used for mammography examinations.

(1) Equipment Design.

(a) FDA Standards. The requirements of 21 CFR 1020.30 and 21 CFR 1020.31 (2006) are adopted and incorporated by reference.

(b) Dedicated Equipment. The x-ray equipment shall be specifically designed for mammography.

(c) Compression. Devices parallel to the imaging plane shall be available to immobilize and compress the breast during mammography procedures.

(d) Image Receptor. The x-ray equipment shall have both an 18 cm by 24 cm and a 24 cm by 30 cm image receptor and moving grids matched to each image receptor size.

(e) Automatic Exposure Control. X-ray equipment used in healing arts screening shall have automatic exposure control capabilities with a post exposure meter which indicates either milliampere-seconds or time values.

(f) Focal Spot. The focal spot size and source to image receptor distance configurations shall be limited to those appropriate for mammography.

(g) Beam Limitation. The x-ray equipment must allow for the x-ray field to extend to or beyond the chest wall edge of the image receptor.

(h) Magnification. X-ray equipment used in a noninvasive manner, requiring techniques beyond those utilized in standard mammography of asymptomatic patients, shall have x-ray magnification capability for noninvasive procedures. The equipment shall be able to provide at least one magnification within the range of 1.4 to 2.0.

(2) Performance Standards.

(a) State Standards. The x-ray equipment shall meet the applicable performance standards in R313-28.

(b) Filtration. The useful beam shall have a half-value layer between the values of the measured kilovolts peak divided by 100 and the measured kilovolts peak divided by 100 plus 0.1 mm of aluminum equivalent. These values are to include the contribution to filtration by the compression device.

(c) Minimum Radiation Output. X-ray equipment installed after the effective date of this rule shall meet the following standard: at 28 kilovolts peak on the focal spot used in routine healing arts screening the x-ray equipment shall be capable of sustaining a minimum output of 500 mR per second for at least three seconds. This output shall be measured at a point 4.5 centimeters from the surface of the patient support device when the source to image receptor distance is at its maximum and the compression paddle is in the beam. Existing x-ray equipment shall meet this minimum radiation output standard within one year of the effective date of this rule.

(d) Exposure Linearity. For kilovolts peak settings used clinically, the exposure per mAs shall be within plus or minus ten percent of the average exposure per mAs for those mAs stations or time stations, if applicable, that are tested.

(e) Automatic Exposure Control. The automatic exposure control mode shall produce consistent film density under changing patient and examination conditions. These conditions include breast thickness, adiposity, kilovolts peak and density settings. This requirement will be deemed satisfied when:

(i) an automatic exposure control technique guide is posted, and

(ii) for a series of films obtained for attenuator thicknesses of two to seven centimeters the resulting radiographic optical densities are within plus or minus 0.2 of the average value when the kVp and density control setting are adjusted as indicated on the technique guide. The attenuator used for determining compliance shall be either acrylic or other tissue equivalent material.

(f) Patient Dose. The x-ray equipment must be capable of giving an average glandular dose to an average size breast of average tissue density that does not exceed 3.0 mGy (0.3 rad) with a grid or 1.0 mGy (0.1 rad) without a grid. This will be deemed satisfied when using an acrylic phantom of 4.5 cm thickness. In addition, under all clinical use conditions, the average glandular dose to the breast must be less than 5.0 mGy (0.5 rad) per film for healing arts screening procedures.

(3) Mammography X-ray Equipment Quality Control.

(a) Initial Installation. Upon completion of the initial installation of the x-ray equipment, and before it is commissioned for clinical use, the equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board. The evaluation results shall be submitted to the Director for review and approval.

(b) Annual Evaluation. At intervals not to exceed 12 months or at the request of the Director, the x-ray equipment shall be evaluated by a mammography imaging medical physicist who has been approved by the Board.

(c) The registrant shall develop and implement a quality control testing procedure for monitoring the radiation performance of the x-ray equipment.

**R313-28-140. Qualifications of Mammography Imaging Medical Physicist.**

(1) An individual seeking certification by the Board for approval as a mammography imaging medical physicist shall file an application for certification either electronically or on forms furnished by the Division. The Board may certify individuals who meet the requirements for initial qualifications. To remain certified as a mammography imaging medical physicist an individual shall get a renewal certification from the director by satisfying the requirements found in Subsection R313-28-140(3).

(2) To meet the initial qualifications the applicant shall:

(a) be certified by the American Board of Radiology in Radiological Physics or Diagnostic Radiological Physics, or the American Board of Medical Physicists in Diagnostic Imaging Physics; and

(b) satisfy the educational and experience requirements in Subsections R313-28-140(2)(b)(i) through R313-28-140(2)(b)(iii):

(i) have a master's or higher degree from an accredited university or college in physical sciences;

(ii) have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(iii) have conducted surveys of at least one mammography facility and a total of at least ten mammography units under the direct supervision of a mammography imaging medical physicist approved by the Board. No more than one survey of a specific unit within a period of 60 days can be counted toward the total mammography unit survey requirement.

(3) The Board's initial certification shall expire three years from the date of the Board's approval.

(a) The director may issue a renewal certification to a certified mammography imaging medical physicist if the individual demonstrates compliance with the requirements in Subsections R313-28-140(3)(a)(i) through R313-28-140(3)(a)(ii). To get a renewal certification, a mammography imaging medical physicist previously certified by the Board shall submit an application to the director either electronically or on forms furnished by the Division demonstrating that the individual has met the requirements in Subsections R313-28-140(3)(a)(i) and R313-28-140(3)(a)(ii) during the immediately preceding three years:

(i) Has earned at least 15 hours of continuing educational credits in mammography imaging; and

(ii) Has performed at least three mammography facility surveys and a total of at least nine mammography unit surveys. No more than one survey of a specific facility within a ten-month period or a specific unit within a period of 60 days can be counted toward this requirement.

(b) The director's renewal certification shall expire three years from the date of issuance.

(c) There is no limitation to the number of renewal certifications that a mammography imaging medical physicist previously certified by the Board may get from the director by demonstrating compliance with the requirements of Subsection R313-28-140(3)(a).

(4) Mammography imaging medical physicists whose initial certification or renewal certification, as the case may be, has lapsed:

(a) may continue to perform surveys if working under the direct supervision of a mammography imaging medical physicist with a current certification or renewal certification; and

(b) may not perform independent surveys before their certification is renewed by the director. To get a renewal certification the individual shall comply with the requirements in Subsection R313-28-140(3)(a).

(c) Renewal certifications for mammography imaging medical physicists whose initial certification or renewal certification, as the case may be, has lapsed for one year or more shall be approved by the Board and may not be approved by the director.

**R313-28-160. Computed Tomography X-ray Equipment.**

(1) Equipment Requirements.

(a) In the event of equipment failure affecting data collection, means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or intercepting the x-ray beam with a shutter mechanism through the use of either a back-up 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 R313-28-160 (1)(a).

(c) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans, of greater than 0.5 second duration.

(2) Tomographic Plane Indication and Alignment.

(a) 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 plane.

(b) If a device using a light source is used to satisfy R313-28-160 (2)(a), the light source shall provide illumination at levels sufficient to permit visual determination of the location of the tomographic plane or reference plane.

(c) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

(3) Beam-On and Shutter Status Indicators.

(a) The computed tomography (CT) x-ray control panel and CT 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.

(a) The CT x-ray system shall be designed such that technique factors, tomographic section thickness, and scan increment shall be indicated prior to the initiation of a scan or series of scans.

(5) Quality Assurance Procedures. Quality assurance procedures shall be conducted on the CT x-ray equipment.

(a) The quality assurance procedures shall be in writing. Such procedures shall include, but not be limited to, the following:

(i) Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

(ii) Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

(b) The parameters measured to satisfy R313-28-160(5)(a)(ii) shall include, but not be limited to, kVp, mA and reproducibility of dose appropriate to the type of CT procedures performed.

(c) Records of tests performed to satisfy the requirements of R313-28-160(5)(a) and (b) shall be maintained for three years for inspection by the Division.

(6) Dose Calibration.

(a) Radiation measurements shall be performed at least annually and after change or replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation measuring instrument shall be traceable to a national standard and shall be calibrated at intervals not to exceed two years.

(c) Measurements shall be specified in terms of the multiple scan average dose, using phantoms and technique factors appropriate to the type of CT procedures performed.

**R313-28-200. Information on Radiation Shielding Required for Plan Reviews.**

In order to evaluate a need for radiation shielding associated with a plan review, the following information shall be submitted to a Qualified Expert so that an adequate review may be performed.

(1) The plans showing, as a minimum, the following:

(a) the normal location of the radiation producing equipment's radiation port, the port's travel and traverse limits, general directions of the radiation beam, locations of windows, the location of the operator's booth, and the location of the x-ray control panel;

(b) structural composition and thickness of walls, doors, partitions, floor, and ceiling of the rooms concerned;

(c) the dimensions, including height, floor to floor, of the rooms concerned;

(d) the type of occupancy of adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest existing occupied areas;

(e) the make and model of the x-ray equipment, the maximum energy output, and the energy waveform; and

(f) the type of examination or treatment which will be performed with the equipment.

(2) Information on the anticipated workload of the x-ray systems in mA-minutes per week.

(3) A report showing all basic assumptions used in the development of the shielding specifications.

**R313-28-300. Additional Requirements Applicable to Certified Systems Only.**

Diagnostic x-ray systems incorporating one or more certified components shall be required to comply with the following additional requirements which relate to the certified component.

(1) Beam limitation for stationary and mobile general purpose x-ray systems.

(a) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(b) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 LUX (15 foot-candles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of the quadrants of the light field. Radiation therapy simulation systems are exempt from this requirement.

(2) Beam Limitation for Portable X-ray Systems. Beam limitation for portable x-ray systems shall meet the additional field limitation requirements of R313-28-51(1) or R313-28-300(1).

(3) Beam limitation and alignment on stationary general purpose x-ray systems equipped with PBL.

(a) PBL shall prevent the production of x-rays when:

(i) either the length or the width of the x-ray field in the plane of the image receptor differs, except as permitted by R313-28-300(3)(c), from the corresponding image receptor dimensions by more than three percent of the SID; or

(ii) the sum of the length and width differences as stated in R313-28-300(3)(a)(i) without regard to sign exceeds four percent of the SID.

(b) Compliance with R313-28-300(3)(a) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(c) The PBL system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor through stepless adjustment of the field size. The minimum field size at a distance of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(d) The PBL system shall be designed so that if a change in image receptor does not cause an automatic return to PBL function as described in R313-28-300(3)(a), then change of the image receptor size or SID must cause the automatic return.

(4) Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

**R313-28-350. Qualifications of Operators.**

Operators of diagnostic x-ray systems must be licensed to practice in Utah in accordance with Title 58 Chapter 54.

(1) The registrant shall document that the operator of diagnostic x-ray equipment is trained in the proper choice of technique factors to be used and in the safe and effective operation of the x-ray equipment.

**R313-28-400. Information to be Submitted by Persons Proposing to Conduct Healing Art Screening.**

(1) Individuals requesting that the Director approve a healing arts screening program shall submit the following information:

(a) name and address of the applicant and, where applicable, the names and addresses of agents within this State;

(b) diseases or conditions for which the x-ray examinations are to be used;

(c) description, in detail, of the x-ray examinations proposed in the screening program including the frequency of screening and the duration of the entire screening program;

(d) description of the population to be examined in the screening program including age, sex, physical condition, and other appropriate information;

(e) an evaluation of known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations; and

(f) written evidence that:

(i) an Investigational Review Board, which has been approved by the United States Food and Drug Administration, has reviewed and approved the healing arts screening program; or

(ii) the United States Food and Drug Administration has approved the use of the x-ray examination for the diseases or conditions of interest.

(2) The Director shall not approve a request for a healing arts screening program unless the submissions required by R313-28-400(1) are determined by the Director to be complete and adequate.

**R313-28-450. Minimum Design Requirements for an X-ray Machine Operator's Booth - New Installations Only.**

(1) Space requirements:

(a) The operator shall be allotted not less than 0.70 square meter (7.5 square feet) of unobstructed floor space in the booth.

(b) The minimum space as indicated above may be geometric configurations with no dimension of less than 0.61 meters (two feet).

(c) The space shall be allotted excluding encumbrances by the console, for example, overhang or cables, or other similar encroachments.

(d) The booth shall be located or constructed to ensure that unattenuated primary beam scatter originating on the examination table or at the wall mounted image receptor will not reach the operator's position in the booth.

(2) Structural Requirements.

(a) The booth walls shall be permanently fixed barriers of at least 2.13 meters (seven feet) high.

(b) When a door or movable panel is used as an integral part of the booth shielding, it must have a permissive device which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of R313-15.

(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 one meter (40 inches) from points subject to primary beam scatter, leakage or primary beam radiation; and

(b) shall allow the operator to use the majority of the available viewing windows.

(4) Viewing system requirements:

(a) When the viewing system is a window:

(i) the viewing window shall have a visible area of at least 0.09 square meters (one square foot);

(ii) regardless of size or shape, at least 0.09 square meters (one square foot) of the window area must be centered no less than 0.6 meters (two feet) from the open edge of the booth and no less than 1.5 meters (five feet) from the floor; and

(iii) the window shall have at least the same lead equivalence of that required in the booth's wall in which it is mounted.

(b) When the viewing system is by mirrors, the mirrors shall be so located as to accomplish the general requirements of R313-28-450(4)(a).

(c) When the viewing system is by electronic means:

(i) the camera shall be so located as to accomplish the general requirements of R313-28-450(4)(a); and

(ii) there shall be an alternate viewing system as a backup for the primary system.

**KEY: dental, X-rays, mammography, beam limitation**

**Date of Last Change: September 15, 2025**

**Notice of Continuation: April 8, 2021**

**Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107**